**Protocol**

**1.0 Title**

Can Hygiene-Therapists maintain the oral health of routine low-risk dental recall patients in high-street dental practices: a pilot study.

**1.1 Researchers**

Professor Paul Brocklehurst, Professor of Health Services Research and Director of NWORTH Clinical Trials Unit, Bangor University;

Professor Christopher Burton, Head of the School of Healthcare Sciences, Bangor University;

Professor Philip Preshaw, Professor of Periodontology, Newcastle University;

Dr Zoë Hoare, Principal Statistician, NWORTH Clinical Trials Unit;

Dr Lynne Williams, Senior Research Fellow; and

Dr Jing Shen, Senior Research Associate (Health Economics), Newcastle University.

**2.0 Background**

The use of General Dental Practitioners (GDPs) 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 are undertaken on low risk patients and result in no further treatment. Hygiene-Therapists (H-Ts) have been shown to be equally efficacious at screening for oral diseases (Brocklehurst et al., 2015; Macey et al., 2015). What is not known is whether they are as effective as GDPs at undertaking the check-up for low risk routine NHS dental patients and whether they could reduce the cost of service provision. This is important as 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, almost half of the population do not regularly attend the dentist and this group has the highest need.

Two earlier NIHR grants have investigated both the efficacy and efficiency of using H-Ts in NHS practices (NIHR/CS/010/004 & HS&DR 11/1025/04) (PRB was CI). The former demonstrated their efficacy (their diagnostic test accuracy) and feasibility of using H-Ts for ‘check-up’s and the latter found that dental practices using H-Ts in the NHS could be better organised to improve efficiency (Macey et al., 2016; Brocklehurst et al., 2016). A pilot study is the next step to inform the design of a definitive trial. This will test whether H-Ts are as good at maintaining the oral health of low-risk routine NHS dental patients (but are a cheaper option) i.e. a non-inferiority design. It will also test cross-overs from the intervention arm to the treatment as usual arm (check-up and treatment by the GDP).

**2.1 Aims and objectives**

The aim of this study is to inform the design for a definitive trial to determine whether H-Ts can maintain the oral health of low-risk routine NHS patients, who form the predominant proportion of the regularly attending practice population. The objectives of this study are to:

1. Determine the most appropriate design of a definitive trial;
2. Determine whether Bleeding on Probing (BoP) is the most appropriate primary outcome measure (and if not, determine the most appropriate measure);
3. Confirm the appropriateness of the non-inferiority margin of the chosen outcome measure for the definitive trial (i.e. whether the effect estimate lies within an appropriate margin of non-inferiority);
4. Further investigate recruitment, retention and fidelity rates;
5. Confirm willingness to be randomised amongst study participants;
6. Determine the potential for patient cross-overs between arms (e.g. where the patient is considered too complex to be managed by the H-T);
7. Rehearse the health economic analysis and pilot the health economic data collection tool to inform the definitive trial design; and explore patients’ preferences in a focus group setting to inform a preference elicitation exercise (e.g. discrete choice experiment) in the definitive trial.
8. Undertake a process evaluation underpinned by a realist framework to understand "what works, for whom, why and in what circumstances?"

**3.0 Methodology**

Three work-streams (WSs) are proposed. WS1 will address objective 1.

An individually randomised pilot study in the North-West of England over a 15 month period is proposed:

* P (Population): adult asymptomatic low-risk routine dentate or partially dentate NHS patients;
* I (Intervention): check-up and any subsequent treatment undertaken by a H-T;
* C (Control): check-up and subsequent treatment by a GDP (‘current practice’); and
* O (Outcome): proportion of sites that bleed on probing (measure of oral cleanliness and periodontal health).

The unit of randomisation will be at the patient level. Primary end-points are pragmatic, based on simple adaptations of indices in common use in practice. Other secondary outcome measures will include:

* Proportion of sites that have visible plaque present (measure of oral cleanliness);
* Proportion of sites with a probing depth that exceeds Code 2 of the Basic Periodontal Examination periodontal probe;
* Number of new decayed and filled teeth;
* Unplanned visits between ‘check-up’s;
* Oral health related quality of life (Oral Health Impact Profile); and
* Patient centred outcomes to explore behaviour change and dental anxiety.

In WS1, 216 (108 in each arm) ‘low risk’ routine dental patients will be recruited across six NHS dental practices in the North-West of England. This accounts for an attrition rate of 30%, which is similar to the attrition rate seen in our feasibility study and other dental practice based trials (Macey et al., 2016; Jones et al., 2011). This is based on the confidence interval approach described by Cocks & Torgerson (2013), that considers the likelihood of the main study finding a relevant effect size. Using the logic that if the observed difference between the groups in the pilot trial is zero, then the upper confidence interval will exclude the estimate that is considered clinically significant in any future trial. For an 80% confidence interval, this will be 9% of the full study design. As a non-inferiority trial will require a larger sample size than a superiority trial, we have considered this to be appropriate for the calculation of an adequate sample for the pilot, to indicate the likelihood of observing a clinical meaningful difference. Assuming that bleeding on BoP is the primary outcome measure in the definitive trial, then taking a non-inferiority margin of 5% a main trial would require a sample of approximately 1,618 and 9% of this is approximately 150 (which becomes 216 when attrition is accounted for).

In the latest epidemiological survey (conducted every decade) (n=11,380), half of all dentate adults reported that they attended the dentist at least once every six months and a further 21 per cent indicated that they attended at least once a year (ADHS, 2009). This means that approaching three-quarters of patients would be seen twice within the 15 month period. This concurs with our experience in the feasibility study, where patients were seen for three ‘check-up’s during the study period (Macey et al., 2016).

WS2 will develop and test the health economic data collection tool, and rehearse the health economic analysis of the intervention compared to the current practice, to inform the definitive trial design. The pilot will adopt the view point of both the NHS and the patient, and collect resource use data which include the costs of dental consultation by GDPs and H-Ts 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 (however ‘unlikely’, and this will inform the definitive trial whether such data collection is necessary and how such data should be collected with minimum burden to the patients and cost to the trial). With regard to effects, we will primarily use the clinical measure and will explore other oral health related quality of life measures, using the Oral Health Impact Profile.

Within WS2, we will also explore patients’ preferences over being seen by H-Ts compared to being seen by GDPs. There may be issues raised on the acceptability and compliance of patients to be seen by H-Ts instead of GDPs, and treatment charges that are considered acceptable by patients to be seen by an H-T. Those can be explored in a focus group setting, and results will be used to prepare a preference elicitation exercise (e.g. discrete choice experiment) in the future definitive trial. The preference elicitation exercise in a definitive trial would then be able to provide a metric to value the benefits of the intervention in monetary terms, inform the implementation and organisation of care and improve patients’ acceptability and compliance.

WS3 will employ a theory-driven approach to understand “what is it about a programme that works for whom, in what circumstances, in what respects, over which duration” (Pawson, 2013). Realist evaluation is a recognised methodology used extensively in health services research, because it recognises the complex and contingent nature which underpins the settings for new interventions and service delivery.

**3.1 Eligibility criteria**

For WS1, practices will be recruited across the North-West of England using the following eligibility criteria:

1. The practice should employ at least one H-T, with at least two years clinical experience;
2. The majority of adult service provision should be in the NHS;
3. The patient should be treated under the NHS; and
4. The practice should have the support of a practice manager.

The eligibility criteria for the individual patients are:

1. NHS adult patient (> 18 years of age) on the recall list of the practice;
2. Has presented with no more than one active lesion in the last year or required no more than one dental filling due to dental caries within the previous year (defined as "low-risk”)
3. Asymptomatic at time of the ‘check-up’;
4. Have no predisposing medical history that elevates risk status;
5. Were seen for their routine recall at least six months ago;
6. Dentate or partially dentate.

New patients, adult patients presenting in pain, patients requiring root fillings or extractions, edentate and those that have or are receiving on-going periodontal treatment will be excluded. Patients with sites that have a BPE code of 3 or above will also be excluded.

**3.2 Patient pathway**

The detailed patient pathway is provided in Figure 1. On arrival for their ‘check-up’, identified patients will be asked by a member of the research team whether they have any questions and if they wish to participate in the study. If they agree, the patient will be asked to sign their Consent Form and a unique patient identifier will be provided to ensure anonymity. A unique patient identifier reference sheet will be kept, which will enable the patients to be tracked, when necessary. The patients will then visit a trained epidemiologist who will first check that the patient is eligible for the study and then will undertake the baseline measurements (see above) for the Case Report Form (CRF). The patient will then be randomised (using NWORTH Clinical Trials Unit’s sequentially randomised dynamic adaptive algorithm) to see a H-T or their GDP.

The patient pathway in the pilot will follow the procedure in the published 15 month feasibility study. Given that half of the adult population do not require any further treatment after a ‘check-up’, the pilot study will only focus on ‘low-risk’ patients. ‘High-risk’, complex or symptomatic patients will be excluded.

In the intervention arm, patients will attend their practice and undergo a ‘check-up’ and any subsequent treatment within the H-Ts’ Scope of Practice. As highlighted earlier, regulatory changes made by the General Dental Council in 2013/14 allow H-Ts to see patients directly, diagnose and undertake all of the routine direct restorative treatment that GDPs can do, except for root fillings. In the feasibility study, no patient cross-overs were seen with the 60 patients recruited. Patients were willing to be randomised and had recruitment and retention rates of 82% and 78% respectively. Records will be kept of those participants who start off in the H-T arm, but cross-over to the control arm because they are considered to be too complex for H-T to manage their care (this was not seen in the feasibility study). At least two ‘check-ups’ are expected in the 15m duration of the pilot. Again, this is consistent with the feasibility study.

Should patients experience pain or present with problems during the study, they will be seen by the H-T initially and then offered appropriate treatment (this was not seen in the feasibility study). This may be with the H-T or the GDP, depending on the presenting problem. All treatment information will be entered onto the CRF, which will record the type of treatment undertaken and the clinician type involved. In the likely event that the patient is deemed healthy, the patient will be placed back on the recall list according to the recommendations of the clinician. Fidelity rates amongst clinicians in the feasibility study were 97%.

Randomisation will be at the individual level (patient) and performed by NWORTH CTU. Treatment allocation will be on a 1:1 basis using a sequentially randomised dynamic adaptive algorithm (Russell et al., 2011). For each participant randomised the likelihood of their allocation to each treatment group is re-calculated based on the participants already recruited and allocated. This re-calculation is done at the overall allocation level, within stratification variables and within stratum level (the relevant combination of stratification levels). By undertaking this re-calculation, the algorithm ensures that balance is maintained within acceptable limits of the assigned allocation ratio while maintaining unpredictability.

WS2 will take place alongside the main pilot trial. The pilot cost-effectiveness analysis will collect costs and effects data on all trial participants. The focus group to explore patients’ preference will select a subsample of the trial participants, and it is anticipated that about 12-30 patients in total will be recruited to take part in two to three focus group discussions. Participants for the focus group will be selected from a broad range (covering different socio-demographic profiles) of consented eligible patients who may or may not participate in WS1.

In WS3, we will use purposive and convenience sampling to identify interview participants. At this stage, we would expect to collect data from a sub-group of WS1 (see below), GDPs and H-Ts, patients and dental commissioners. Given the inclusion criteria, we will be focusing on ‘low-risk’ dental patients, but we will seek to recruit across the age-range for adults and ensure a culturally and ethnically diverse sample, as far as possible. We will take a systems wide approach to the evaluation, as we argue that facilitating implementation and change in complex interventions are affected by macro and meso level factors in addition to those identified at micro/individual level. In this way, we can identify the systems level triggers, as well as individual behaviour change factors. As a result of this, we would also expect to contact the Chief Dental Officers.

**3.3 Data collection**

Trained epidemiologists will act as blinded external assessors in WS1. The proposed primary outcome measure is the number of sites that bleed on probing (BoP). BoP is both relevant to clinicians and relevant to patients. It is stable, measurable and would change over the timescale of the project. BoP is the primary outcome measure used in three of the four on-going/recent NIHR HTA trials in a primary dental care setting (IQuAD, INTERVAL, INCENTIVE). Other measures of periodontal health (e.g. pocket depths) are more sensitive to measurement bias and take a long time to express a smaller effect (Imrey, 1986).

Dental caries has been chosen as a secondary rather than a primary outcome measure. This is because it has a relatively low prevalence and a long time to expression in routine NHS adult patients. This was evidenced in the 15m feasibility study (Macey et al., 2016). In contrast, BoP is widespread and a relatively sensitive measure of oral health. BoP is routinely assessed in clinical practice to measure the degree of gingival and periodontal inflammation. Whereas the presence of bleeding on probing at isolated sites is not a particularly good indicator of risk for future disease progression (Lang et al., 1986), absence, or minimal levels, of BOP are a very good indicator of periodontal health and tissue stability (Chapple, 1997; Lang et al., 1990). BoP provides an indication of inflammation in the gingival and periodontal tissues. It is also highly relevant to patients, who often complain of bleeding gums as a first sign of gingival and periodontal problems. As a result, this pragmatic primary end-point is very relevant to both patients and clinicians, and has high generalizability to every-day clinical practice. Furthermore, within the context of the pilot, which will recruit primarily dentally healthy patients and assess whether H-Ts are able to safely undertake ‘CHECK-UP’s, BoP is the most sensitive measure to signs of developing gingival inflammation. Participants will also be asked to complete questionnaires to record their experience of the procedures, any anxiety and their quality of life (OHIP) (as detailed above).

NHS resource use (primary and secondary dental services) data for WS2 will be collected in the CRF. Patients’ use of dental health services and out of pocket expenses related to dental problems during the trial’s follow-up will be collected through the development and application of a participant costs questionnaire (PCQ). PCQ will be distributed every 6 months following randomisation. Data on effects will be collected for the primary outcome of the proportion of sites that bleed on probing as well as through patient reported outcome measures, such as oral health related quality of life measured by OHIP.

Focus group discussions will be conducted alongside the main trial using a group of consented eligible patients. Eligible patients will be asked whether they are interested in participating in a separate focus group discussion regardless of whether they want to participate in the main trial, where questions on their preferences and views of being seen by H-Ts or GDPs will be asked and discussed. After gaining consent, the focus groups will be undertaken at the practice and interview questions will be informed by the PPI group, expert panel (clinicians and experts in the study team) and the developing programme theory from WS3. The focus groups are expected to last for approximately one hour. The audio-taped interviews will be transcribed and analysed and anonymised. The focus group formats and questions will be informed by the literature on qualitative research methodology used for designing a discrete choice experiment (the detail of the likely domains are provided in Appendix 1).

WS3 will be undertaken over three phases. In Phase 1, a review of extant literature and structured discussions with practitioners (e.g. GDPs and H-Ts) and commissioners will contribute to the development of an initial theoretical framework representing a hypothetical model of successful intervention implementation. This work will be produced jointly with stakeholders using meetings and workshop-type events to test out ideas and propositions with a range of people who use the intervention.

In Phase 2, empirical data collection methods will include video diaries (n=10) and semi-structured interviews with participants in WS1 (n=20) to test and refine the initial programme theory. The purpose of using video diaries is to provide participants with an opportunity to reflect on their experiences of the intervention, and to enable data about participants’ interpretations and perceptions of the intervention to be captured. Video diaries provide another dimension to the data, and will ensure robust testing and refining of the initial programme theory. This will be undertaken after the literature review (see Figure 2).

Data collection will focus on implementation issues for different participant groups. For example, for practitioners and commissioners, perceptions of acceptability, additional cost and adherence may influence the success or otherwise of the intervention. There may also be external factors to consider which relate to how the intervention is perceived. A semi-structured interview schedule will be developed (in collaboration with the PPI group). Audio-taped interviews will be conducted in person and via the telephone (as appropriate) and will last up to 60 minutes. Data will be anonymised, fully transcribed, and analysed by co-applicants CB, LW and PRB.

**3.4 Data analysis**

From the perspective of effectiveness, initial analysis will focus in WS1 on the width of the non-inferiority margin for the primary outcome measure and differences in means and proportions for the secondary outcome measures. The effect estimate will be the difference in means between the two arms and will be evaluated with respect to clinical and statistical significance. The remaining clinical and patient reported outcomes will be analysed similarly and interpreted. Analyses will be made on an intention-to-treat basis. The selection of co-variates for the models will include those considered as possible stratification variables (dental practice size, deprivation, previous history of disease, number of teeth remaining). The process of selection and inclusion of co-variates will be fully detailed in the statistical analysis plan that will be developed and agreed before completion of data collection.

The confidence interval around the effect estimate will be considered for the outcomes measured. Consideration of whether this “effect” lies within a reasonable proposed non-inferiority margin will feed into the decision on future design of the trial. If evidence indicates that there is potential for the treatment to be considered superior then future design will be influenced. This indicative cut off will be defined in the full statistical analysis plan that will be drawn up prior to completion of data collection. As part of the analysis of the pilot data we will assess the possibility of there being a significant intra-cluster correlation with regard to the primary outcome measure. This would then be included in the sample size calculations for a future definitive trial.

In WS2, we will rehearse the health economic analysis comparing the cost-effectiveness of using H-Ts with using GDPs for routine check-ups of low risk patients. For each participant, use of resources will be combined with unit costs to provide a cost for that participant, and then a mean cost per patient for each arm calculated. The effect of the intervention will be primarily measured by the clinical indicator – the proportion of sites that bleed on probing. We will also consider oral health related quality of life (measured by OHIP) as the effect of the intervention. Changes in the clinical measure between baseline and end of the follow-up will be calculated for each arm as effectiveness. Mean cost and effectiveness per patient will be derived for each arm. Differences in mean cost and effectiveness between two arms will then be used to estimate incremental costs, incremental effectiveness and incremental costs per unit change in the proportion of sites that bleed on probing. These data will be presented as point estimates. Uncertainty in parameter estimates will be addressed through the application of the bootstrapping technique that produces confidence intervals around estimates of the means. The results of this stochastic analysis will be presented as cost and effectiveness plots and as cost-effectiveness acceptability curves. Deterministic sensitivity analysis will be used to explore other uncertainties such as alternative cost estimates.

The focus group discussions of patients’ preference on being seen by H-Ts or GDPs will help prepare a preference elicitation exercise (e.g. discrete choice experiment) in the future definitive trial to predict patients’ compliance of attending H-T appointments and provide recommendations for the organisation of care. We will prepare a list of possible characteristics of both being seen by H-Ts and GDPs based on trial data, literature search and expert opinions. The participants will be asked to rank those characteristics from the most important to least important in their view. Participants will also be encouraged to discuss their views on the intervention and suggest any other concerns they may have. Data collected from the focus group discussions will be listed in a table and grouped by themes with illustrative anonymised quotes, and results will be summarised and presented at the end of the health economic report to provide recommendations for conducting a preference elicitation exercise in the future definitive trial.

In WS3, data analysis will follow a recognised approach to enable the testing and refining of the CMO configurations. The principles of framework analysis (Spencer, 2014) will be used to analyse data across WS3. Interview transcripts will be transcribed and analysed using a deductive coding framework based on the initial programme theory. The main approach to analysis will be the use of abductive reasoning to seek patterns (demi-regularities) from and within the CMO configurations. Data from the video diaries will be integrated within this process.

**4.0 Ethical issues**

Patient safety might be thought to be a concern, however, previous research undertaken by the same Chief Investigator has shown that H-Ts are safe as front-line healthcare workers (in terms of detecting oral cancer and its precursors). Two large National Institute of Health Research grants (NIHR) (led again by the Chief Investigator) has also shown that H-Ts are as good as dentists in the detection of tooth decay and gum disease. In addition, changes made by the dental regulator in 2013 now allow patients to ‘directly-access’ H-Ts for their care. This study will explore whether H-Ts can be used to maintain the health of ‘low risk’ regular dental attenders.

Patient acceptability is another potential concern, but results from earlier studies suggest that this is positive (including a published feasibility study and a separate large NIHR project). However, the purpose of the study will be fully explained in the Information Sheet and patients will have the opportunity of asking any questions to the dental team at the practice, prior to being consented.

The study will be managed in accordance with Good Clinical Practice and overseen by NWORTH Clinical Trials Unit, using a dedicated trial manager. The Chief Investigator is Director of the Unit, which is registered with the UKCRC and has detailed Standard Operating Procedures.

Patient confidentiality is also a key priority and all record forms from the study will be anonymised. All forms and files will be kept securely on a password protected PC and any paper records kept in a locked drawer in the Chief Investigator’s Office.

**4.1 Oversight**

The governance and management of the study will be undertaken by NWORTH, a UKCRC accredited Trials Unit. As a result, the study will adhere to NWORTH’s Standard Operating Procedures, for all trial and data management, statistical and regulatory matters. Best practice will be employed throughout to ensure this project is managed to the highest possible standard. Appropriate supervision and training of project-specific staff and training in Good Clinical Practice will be ensured. Trial-specific training requirements will be addressed throughout the study period and regularly reviewed. NWORTH’s Quality Assurance Officer will co-ordinate oversight of monitoring, documentation and all aspects of quality management and regulatory issues. NWORTH’s Senior Trials Manager will provide advice to the management team on all aspects of the running of the study.

The research will be sponsored by Bangor University. The Trial Steering Committee will consist of an independent chair, independent and PPI representatives. The group will oversee the running of the trial on behalf of the Sponsor (Bangor) and funder (NIHR HS&DR) and will have overall responsibility for the continuation or termination of the trial. It will ensure that the trial is conducted in accordance with the principles of Good Clinical Practice and the relevant regulations, and to provide advice on all aspects of the study.

**APPENDIX 1: Likely domains for the focus groups**

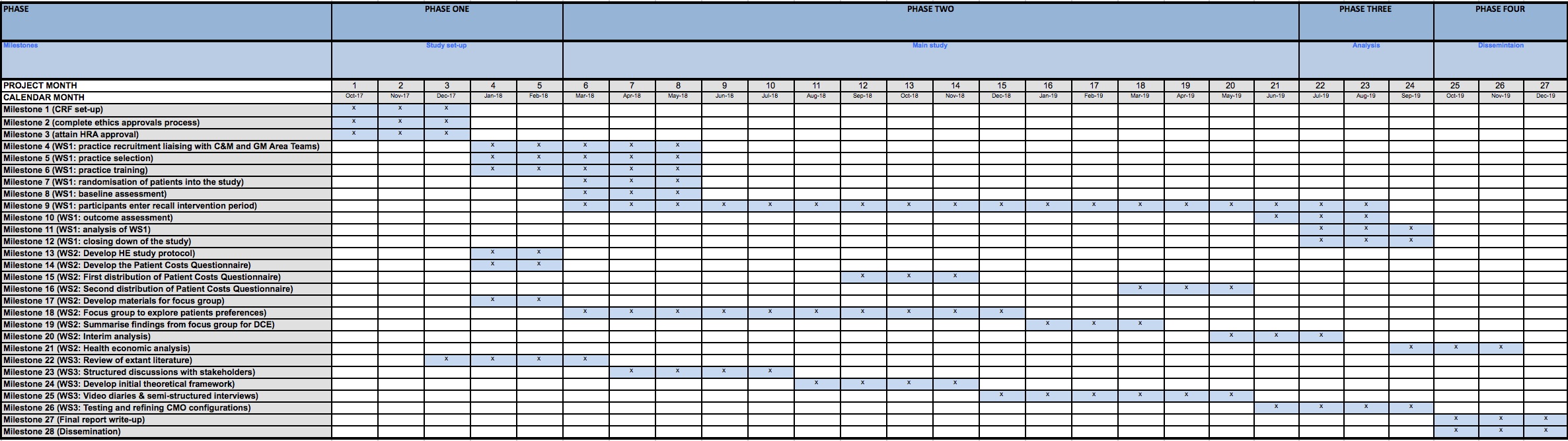
Although informed by the literature review and initial programme theory, the likely domains are as follows:

* What factors act as barriers and enablers to implementation?
* Acceptability;
* Cost and adherence;
* External factors which facilitate/hinder implementation;
* Local practice; and
* Integration with existing services.

**Figure 1: Patient pathway**

**Macintosh HD:Users:sps602:Documents:DENTAL PUBLIC HEALTH:Grants:F006555_NIHR HS&DR 2016:NEXT STEPS:Patient flow_HS&DR pilot.pdf**

**Figure 2: Gantt chart**

****

**REFERENCES**

Adult Dental Health Survey 2009 (Technical information). Appendix 2. Available at: http://www.dhsspsni.gov.uk/adhtechnical\_information.pdf. Downloaded 27 July 2016.

Brocklehurst P, Ashley J, Walsh T, Tickle M. Relative performance of different dental professional groups in screening for occlusal caries. Community Dentistry and Oral Epidemiology 2012;40:239-246.

Brocklehurst P, Macey R. Skill-mix in preventive practice – will it help in the future? BMC Oral Health 2015;15(Suppl 1):S10. DOI: 10.1186/1472-6831-15-S1-S10

Brocklehurst P, Mertz B, Jerković-Cosić K, Littlewood A, Tickle M. Direct access to midlevel dental providers: an evidence synthesis. Journal of Public Health Dentistry 2014;74:326-335.

Brocklehurst P, Pemberton M, Macey R, Cotton C, Walsh T, Lewis MAO. Comparative test accuracy of different members of the dental team for malignant and non-malignant oral lesions. Br Dent J 2015;218(9):525-9.

Chapple ILC. Periodontal disease diagnosis: current status and future developments. J Dent 1997;25:3-15.

Clarkson JE, Ramsay CR, Averley P, Bonetti D, Boyers D, Campbell I, Chadwick GR, Duncan A, Elders A, Gouick J. IQuaD dental trial: a multicentre randomised controlled trial comparing oral hygiene advice and periodontal instrumentation for the prevention and management of periodontal disease in dentate adults attending dental primary care. BMC oral health 2013;13:58.

Cocks K, Torgerson DJ. Sample size calculations for pilot randomized trials: a confidence interval approach. J Clin Epidemiol. 2013 Feb;66(2):197-201. doi: 10.1016/j.jclinepi.2012.09.002.

Craig P, Dieppe P, Macintyre S, Michie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;337:1655.

DH 2014. NHS dental contract pilots – Learning after first two years of piloting. Available at:

https://http://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/282760/Dental\_contract\_pilots\_evidence\_and\_learning\_report.pdf . Accessed 10th September 2016.

Dyer TA, Brocklehurst P, Glenny AM, Davies L, Tickle M, Issac A, Robinson PG. Dental auxiliaries for dental care traditionally provided by dentists. Cochrane Database of Systematic Reviews 2014, Issue 8. Art. No.: CD010076. DOI: 10.1002/14651858.CD010076.pub2.

Eldridge SM, Lancaster GA, Campbell MJ, Thabane L, Hopewell S, Coleman CL et al. Defining Feasibility and Pilot Studies in Preparation for Randomised Controlled Trials: Development of a Conceptual Framework. PLoS ONE 2016;11(3): e0150205. doi:10.1371/journal.pone.0150205

Galloway J, Gorham JML, Richards D, Russell D, Russell I, Welshman J. The professionals complementary to dentistry: systematic review and synthesis. Available at: http://www.nationalelfservice.net/cms/wp-content/uploads/2012/03/PCD-Review-complete.pdf . Accessed 10th September 2016.

Godson JH, Williams SA, Csikar JL, Bradley S, Rowbotham J. Dental therapy in the United Kingdom: part 2. A survey of reported working practices. Br Dent J 2009;207:417-423.

Gomes M, Gutacker N, Bojke C, Street A. Addressing Missing Data in Patient‐Reported Outcome Measures (PROMS): Implications for the Use of PROMS for Comparing Provider Performance. Health economics 2015 Mar 5. doi: 10.1002/hec.3173.

House of Commons Health Committee. Dental Services. Fifth Report of Session 2007–08. Available at: http://www.publications.parliament.uk/pa/cm200708/cmselect/cmhealth/289/289i.pdf . Accessed 10th September 2016.

HSCIC 2015. NHS Dental Statistics England 2014/15. http://www.hscic.gov.uk/catalogue/PUB18129/nhs-dent-stat-eng-14-15-rep.pdf Accessed 10th September 2016.

Innes NP, Evans DJ. Evidence of improved access to dental care with direct access arrangements. Evidence-based Dentistry 2013;14:36-37.

INTERVAL. Available at: http://www.nets.nihr.ac.uk/projects/hta/063599. Accessed 10th September 2016.

Jones CL, Milsom KM, Ratcliffe P, Wyllie A, MacFarlane TV, Tickle M. Clinical outcomes of single-visit oral prophylaxis: a practice-based randomised controlled trial. BMC oral health 2011;11:35-35.

Lang NP, Joss A, Orsanic T, Gusberti FA, Siegrist BE. Bleeding on probing. A predictor for the progression of periodontal disease? J Clin Periodontol 1986; 13: 590-596.

Lang NP, Adler R, Joss A, Nyman S. Absence of bleeding on probing. An indicator of periodontal stability. J Clin Periodontol 1990; 17: 714-721.

Laurent M, Reeves D, Hermens R, Braspenning J, Grol R, Sibbald, B. Substitution of doctors by nurses in primary care. Cochrane Database of Systematic Reviews 2009;10.1002/14651858.CD001271.

Macey R, Glenny A, Walsh T, Tickle M, Worthington H, Ashley J, Brocklehurst P. 2015. The Efficacy of Screening for Common Dental Diseases by Hygiene-Therapists A Diagnostic Test Accuracy Study. J Dent Res. 2015 Mar;94(3 Suppl):70S-78S. doi: 10.1177/0022034514567335.

Macey R, Glenny A-M, Brocklehurst PR. Feasibility Study: Assessing the Efficacy and Social Acceptability of Using Dental Hygiene-Therapists as Front-Line Clinicians. Br Dent J 2016. MSS-2016-452 (accepted).

Marchal B, Westhorp G, Wong G, van Belle S, Greenhalgh T, Kegels G, Pawson R. Realist RCTs of complex interventions - an oxymoron. Soc Sci Med. 2013 Oct;94:124-8.

May C & Finch T. Implementing, embedding, and integrating practices: an outline of normalization process theory. Sociology 2009;43:535-554.

Moore GF, Audrey S, Barker M, Bond L, Bonell C, Ha’check-up’man W, Moore L, O’Cathain A, Tinati T, Wight D, Baird J. Process evaluation of complex interventions: Medical Research Council guidance. BMJ 2015;350:h1258.

Five Year Forward View. Available at: http://www.england.nhs.uk/wp-content/uploads/2015/03/business-plan-mar15.pdf . Accessed 10th September 2016.

Pawson R. The Science of Evaluation: A Realist Manifesto. London: Sage Publications; 2013.

Prudent Healthcare. Available at: http://www.prudenthealthcare.org.uk. Accessed 10th September, 2016.

Randell R, Greenhalgh J, Hindmarsh J, Dowding D, Jayne D, Pearman A, Gardner P, Croft J & Kotze A. Integration of robotic surgery into routine practice and impacts on communication, collaboration, and decision making: a realist process evaluation protocol. Implementation Science 2014;9:52.

Russell D, Hoare ZSJ, Whitaker R, Whitaker CJ, Russell IT. Generalised method for adaptive randomisation in clinical trials. Statistics in Medicine 2011;30(9):922–934.

Sibbald B, SHEN J, McBride A. Changing the skill-mix of the health care workforce. Journal of health services research & policy 2004;9:28-38.

Slade GD, Spencer AJ. Development and evaluation of the Oral Health Impact Profile. Comm Dent Health 1994 11(1):3-11.

Spencer L, Ritchie J, Ormston R, O’Connor W & Barnard M (2014). Chapter 10 Analysis: Principles and Processes. In Ritchie J, Lewis J, McNaughton Nicholls C, & Ormston R. (2014). Qualitative Research Practice. London. Sage. 269-345

Steele J. NHS dental services in England. London: Department of Health; 2009

Tappin D, Bauld l, Purves D, Boyd K, Sinclair l, Macaskill S, Mckell J, Friel B, McConnachie A, de Caestecker l, Tannahill C, Radley A, Coleman T. Financial incentives for smoking cessation in pregnancy: randomised controlled trial. BMJ 2015;350:h134 doi: 10.1136/bmj.h134

Turner S, Tripathee S, Macgillivray S. Benefits and risks of direct access to treatment by dental care professionals: A rapid evidence review. General Dental Council; 2012.

Watt RG, Steele JG, Treasure ET, White DA, Pitts NB, Murray JJ. Adult Dental Health Survey 2009: implications of findings for clinical practice and oral health policy. Br Dent J 2013;214:71-75.

White IR, Royston P, Wood AM. Multiple imputation using chained equations: Issues and guidance for practice. Statistics in Medicine 2011:377-399.

WHO. Framework for Action on Inter-professional Education & Collaborative Practice. Available at: http://whqlibdoc.who.int/hq/2010/WHO\_HRH\_HPN\_10.3\_eng.pdf?ua=1 . Accessed 10th September 2016.