

A cluster randomised controlled trial in primary dental care based intervention to improve professional performance on routine oral examinations and the management of asymptomatic impacted third molars: study protocol

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Abstract

Background: Routine oral examination (ROE) refers to periodic monitoring of the general and oral health status of patients. In most developed Western countries a decreasing prevalence of oral diseases underpins the need for a more individualised approach in assigning recall intervals for regular attendees instead of systematic fixed intervals. From a quality of care perspective, the effectiveness of the widespread prophylactic removal of mandibular impacted asymptomatic third molars (MIM) in adolescents and adults is also questionable. Data on the effectiveness of appropriate interventions to tackle such problems and for promoting continuing professional development in oral health care are rare.

Methods/Design: Cluster randomised controlled trial with groups of GDPs as the unit of randomisation. The aim is to determine the effectiveness and efficiency of small group quality improvement on professional decision making of general dental practitioners (GDPs) in daily practice. Six peer groups ('IQual-groups') shall be randomised either to the intervention group I or group II. Groups of GDPs allocated to either of these arms act as each other's control group. An IQual peer group consists of 8-10 GDPs who meet in monthly structured sessions scheduled for discussion on practice related topics. GDPs in both trial arms receive recent developed evidence-based clinical practice guidelines (CPG) on ROE or MIM respectively. The implementation strategy consists of one interactive IQual group meeting of mostly 2-3 hours. In addition, both groups of GDPs receive feedback on personal and group characteristics and are invited to make use of web-based patient vignettes for further individual training on risk assessment policy. Reminders (flow charts) will be sent by mail several weeks after the meeting.

The main outcome measure for the ROE-intervention group is the use and appropriateness of individualised risk assessment in assigning recall intervals and for the MIM-intervention group the use and appropriateness of individualised mandibular impacted third molar risk management. Both groups act as each other's controls group.

Pre-intervention data will be collected in study months 1-3. Post-intervention data collection will be performed after 9 months.

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Background

Routine oral examination (ROE) refers to periodic monitoring of the general and oral health status of patients. The main purpose of ROEs is to prevent the onset of oral diseases and/or prevent further progression. This allows the introduction of preventive interventions at the appropriate time and reduces the need for operative interventions. In most developed Western countries a decreasing prevalence of oral diseases underpins the need for a more individualised approach in assigning recall intervals for regular attendees instead of systematic decision making of fixed intervals. In The Netherlands, about 80% of the population regularly visits the dentist for a check-up mostly twice a year (1). This implies that many healthy individuals are scheduled for routine oral screening. In 2000, 50% of the Dutch GPs assigned all their regular patients for routine oral examinations twice a year (2), irrespective of level of risk for oral disease. The efficiency of this systematic monitoring system is still disputed not only in The Netherlands but also internationally (3-10). Recently, two systematic reviews (11,12) and a clinical practice guideline (CPG) advocated an individualised risk based assessment strategy given the lack of good scientific evidence (13). Not only is the ROE-recall debated, also the effectiveness of the widespread prophylactic removal of mandibular impacted asymptomatic third molars (MIM) in adolescents and adults is questioned from a quality of care perspective (14-16).

Recent implementation studies in medical care indicate that evidence on the effect of single interventions is mixed (18-19). It is as yet unclear how quality of oral care provision in dental practice can be improved. Research data on effectiveness of interventions to promote continuing professional development for dentists are rare (17). A previous study showed that small group education sessions did improve the knowledge in dentists, but did not change their clinical behaviour (20). The aim of the present study is to evaluate whether a multifaceted strategy can enhance oral health care according to evidence-based dental practice. Consensus-based CPGs on ROEs (13) and on the management of MIMs (20) are available for educational purposes in clinical practice.

Aim of the study

To determine the effectiveness and efficiency of small group quality improvement on professional decision making of general dental practitioners (GDPs) concerning risk assessment in ROEs (including assigned recall intervals) and risk management of MIMs for patients (children and adults) in dental practice.

Scientific hypothesis

Multifaceted implementation of consensus-based clinical practice guidelines (CPGs) for GDPs on ROEs and the management of MIMs in daily dental practice is more effective and efficient compared to dissemination of CPGs only.

Methods

Study Design

The study is a cluster-randomised trial with incomplete block design. In one trial arm the intervention focus on individual recall decision-making performing ROEs. In the second arm the intervention focus on monitoring and decision-making regarding prophylactic removal versus retention of MIM. Groups of GDPs allocated to either of these arms act as each other's control group. To reduce potential contamination, groups of GDPs are randomised rather than individual GDPs (Figure 1). We assumed that the two clinical conditions (or practices) were largely independent of one another, i.e. performing one would not necessarily influence the other. In the ROE-group the CPG only mentions the necessity of third molars screening in general as a final stage in the dentition development. In the MIM-group the CPG provides an extensive but specific decision-making algorithm i.e. how to deal with mandibular asymptomatic impacted third molars.

Recruitment of GDPs and inclusion/exclusion criteria

Dental peer groups ("IQual-group"), each comprising at least participating GDPs, are the unit of randomisation. An IQual group consists of GDPs, who attend monthly sessions scheduled for discussion on practice related topics as part of a quality assurance program. Participants in peer groups generally support quality improvement procedures, and are experienced in continuing dental education and professional cooperation. The Dutch Dental Association (NMT) has initiated this system and supports nationwide dental peer groups extensively, e.g. offering professional support, feed back and continuing education programmes. All IQual-groups were invited to participate in this study (by means of a newsletter on the website of the NMT), depending on the ability to start within 2-3 months. Those groups that were interested to participate, were invited to visit

a special section of the NMT website (www.NMT.nl) for peer groups only on which more detailed information on the project was given.

GDPs inclusion criteria

The inclusion criteria consisted of:

GDPs who work for at least for three days a week in general dental practice; GDPs who have practiced for at least three years; have a patient population consisting of regular attendees and manage their patient records electronically.

GDPs had to give their informed consent for the assessment and evaluation of electronic patient records. Patient data are collected anonymously.

Patient's inclusion criteria

To be eligible for inclusion, patients should fulfil several criteria, depending on the IQual's CPG to be used (ROE or MIM):

ROE:

All patients that have visited regularly the same dentist (at least once a year) for ROEs over the preceding three years will be included in the study.

MIM:

All patients that have visited regularly the same dentist (at least once a year) for ROEs over the preceding three years are included for the study and, in addition, patients should be between 17 and 35 years of age, and with disease-free impacted mandibular third molars in retention.

Patient's exclusion criteria

ROE:

Patients with symptomatic driven (emergency) attendance in dental practice, or recently started regular attendance in the participating dental practice (within past three years).

MIM:

Patients with symptomatic third molars in dental practice, or recently started regular attendance (past three years) or who already had their third molars removed.

Intervention

Implementation strategy

Participants in both trial arms receive a recent developed evidence-based CPG on ROE or MIM. The implementation strategy consists of 1 interactive IQual group meeting of mostly 2-3 hours with a minimum of 8 GDPs each. These meetings intend to discuss the selected intervention topic and to achieve a more risk-based decision-making process

guided by the CPG. Topics regarding risk management like identification of risk factors/indicators, preventive interventions, prognosis, monitoring, record keeping and recall assignment are presented. In addition, all participants receive feedback from personal and group characteristics retrieved from pre-test questionnaire and specific record forms, and are invited to make use of web-based patient vignettes for further individual training on risk assessment policy (linked to intervention topic with immediate feedback to recommendations of CPG). These vignettes (risk profiles) were developed by means of structured consensus procedures (modified Delphi) with expert groups consisted of acknowledged GDPs and oral surgeons in special fields. In addition, reminders (flow charts) and written patient leaflets with information on the topic are provided during the trial period. Flow charts comprise algorithms of decision-making aspects linked to the trial arm allocation. Depending on the allocated trial arm participants are subjected to a set of planned interventions as described in Table 1.

Randomisation

After their commitment to participate, 60 GDPs nested in 6 IQual groups were randomly assigned (using SPSS) as groups to the ROE or MIM-arm by an independent secretary, not familiar with the groups. The unit of randomisation was the IQUAL group.

Outcomes and instruments

ROE-study

Table 2 lists the outcome parameters and instruments used.

The primary outcome measure for the ROE-study and control group is the use and appropriateness of individualised risk assessment assessed through the assigned recall intervals (in months). The appropriateness will be assessed as follows:

- For high-risk children and adolescents (0 to 18 years): recall intervals of less or equal than 7 months should be assigned. For those with a low risk profile, an assigned recall of more than 7 months is considered appropriate.
- For high-risk adults (18 years and older): recall intervals of less than 9 months should be assigned. For those with a low risk profile equal or more than 9 months is considered appropriate.

The secondary outcome measures for the ROE-study and control group are:

1. The use and appropriateness of individualised risk-based assessment in prescribing bitewing radiographs (BWs) in months. The appropriateness will be assessed as follows:
 - For high caries risk children and adolescents (0 to 18 years): BW-frequencies prescription of less than 24 months are determined as appropriate, and for those with a low caries risk profile BW-frequencies prescription equal or more than 36 months.

- For high caries risk adults (18 years and older): BW-frequencies prescription less than 36 months are determined as appropriate, and for those with a low caries risk profile BW-frequencies prescription of equal or more than 48 months.
2. The use and appropriateness of individualised communication/feed back and advice in patients with a periodontal risk DPSI-score >1 and present dental caries experience. The appropriateness will be assessed as follows:
- The proportion of patients per GDP receiving appropriate preventive advice/feedback, will be calculated.
- Furthermore, as secondary outcome measure, professional role perceptions and compliance concerning the recommendations of the ROE-CPG is assessed by means of questionnaires, provided at the start and at the end of the study.
3. Resource use is documented for an economic evaluation:
- The type of recall interval (months) per GDP over the past 3 years
 - BW-radiographs and other types of radiographs per GDP over the past 3 years
 - Type of performer of ROEs: GDP versus oral hygienist/dental auxiliary
 - Additional interventions per GDP (i.e. polishing stains/removing dental calculus) encompassed at ROEs over the past 3 years.

MIM-study

For the MIM-study and control group, the primary outcome is the use and appropriateness of individualised mandibular impacted third molars risk management.

The appropriateness will be assessed as follows:

- Patients (18-30 years of age) with removed versus retained MIMs over the past five years related to the proportion of patients aged between 18-35 years of age per practice
- Radiographs used for monitoring patients as mentioned above to perform a risk based assessment and prognosis of MIM over the past five years.

As secondary outcome measure professional's attitudes and compliance concerning the recommendations of the MIM-CPG and feedback/information towards patients by means of interviews of patients to confirm risk based performance.

All data will be collected using special registration forms, to be filled in by GDPs and patient records available in practices. Questionnaires, patients' records and registration forms will provide information to assess all outcome parameters. The structured registration forms were used in a previous self-recording study (23).

Data collection

After their informed consent to participate, GDPs will be invited to fill out on beforehand a questionnaire in order to collect personal and practice characteristics and aspects of

attitude and compliance. Individual assessment of electronic patient records with regard to the outcome measures combined with a special registration form (to be applied individually in daily practice) will be used in the evaluation period.

Baseline information will be collected immediately at start (before randomisation of groups), and a first evaluation at the end of the trial after seven to nine months. Each GDP will be instructed to complete at least 20 forms per registration period. As each peer group consists of at least 8 participants, and each arm should hold 3 groups, this will result in a minimum of 480 registrations per trial arm. Finally, questionnaires will be collected from GDPs and co-workers (patients) to assess acceptance and applicability

Sample size

The primary outcome measures in this study are collected from individual patients, who are clustered within GDPs. GDPs are clustered within (existing) IQual groups, which have been randomised to one of the two arms of the trial. The power calculation assumes that the primary outcomes are dichotomous measures, although some outcomes might be treated as continuous measures as well. On the basis of previous research and experience with IQual groups, we expect a relatively high clustering of scores within GDPs, for instance, ICC was 0.29 for recall interval (23) and low clustering within IQUAL groups (changing professional behaviour is largely determined by other factors). We use the ICC for clustering in IQual groups, because this was the unit of randomisation. We aim at a 20% change on primary outcomes (e.g. 20 to 40% patients receive individualised recall intervals). Assuming a power of 80%, $\alpha = 0.05$ and an effect size of 20% for both interventions and an estimated Intra Cluster Coefficient (ICC) of 0.03 based on previous estimates (21-22), the (Aberdeen) power calculation (www.abdn.ac.uk/hsru/epp/cluster.shtml) revealed that 6 IQual groups (60 GDPs) should comprise 150 registrations (patients) per group, resulting in at least 450 registrations in each trial arm.

Statistical analysis

The primary analysis will be performed on an intention-to-treat-analysis.

Secondly, measures will be constructed in particular algorithms to define the appropriateness in variables. Thirdly, the impact on each of the primary and secondary outcomes will be estimated separately, using random effects regression models (linear or logistic) to take into account the clustering of data. These basic models include group allocation (intervention, control), measurement timing (baseline, post-intervention), and interaction of group allocation and measurement timing (=intervention effect). Fourthly, prognostic factors for the outcome (which may be confounders) will be added to the models, like patients' recall interval preferences, which varies from those assigned by

GDPs as well as the preferences regarding the prescription of radiographs by patients/GDPs. In addition this also counts for GDPs and patients' preferences regarding removal versus retention of asymptomatic impacted third molars. Fifthly, a limited number of subgroup analyses will be performed, including an analysis of effectiveness in participants which performed all activities as planned (education session, online training program, helpdesk (= efficacy analysis)).

Economic evaluation

An economic evaluation is performed to estimate the cost-effectiveness of the implementation intervention. This study takes a health care perspective and a time horizon that is similar to the implementation trial.

Effectiveness

The effects are defined in terms of professional performance, because measuring health outcomes or health utilities is beyond the scope of the study. Outcome measures will be the same as in the trial (e.g. oral health risks assessment performance and guideline adherence regarding individual recall assignment and individual monitoring of impacted asymptomatic third molars) and extracted from the trial data.

Costs

Costs considered are those used for the implementation (time for participation by GDPs, preparation time, use of materials) and for changes (if any) in professional performance (recall intervals between successive ROEs, total number of radiographs, both based on individual risk assessment). Oral care unrelated to the topic of the interventions within the observed time period will not be considered. Resource use will be extracted from trial data, where possible, or collected separately for the purpose of the economic evaluation. Costs will be valued according to prevailing Dutch guidelines for economic evaluations and alternatively according to the current national fee coding list for individual oral treatment procedures in general dental practice.

Analysis

An incremental cost effectiveness ratio (ICER) is constructed, which expresses the ratio of differences of costs and effects between the study groups (for each of the two clinical topics). Uncertainty will first be examined in one-way sensitivity analyses of the most influential factors. Finally, a non-parametric bootstrap re-sampling analysis will be performed, which provides a cost-effectiveness plane for a simulated sample of 1000 drawings (with put back) from the pool of observed cost-effect pairs.

Table 1 Outcome parameters and instruments

Outcome parameter	Instruments
<p>Primary ROE-outcomes:</p> <p><u>Clinical Performance/decision making:</u> Number of patients per GDP with assigned recall interval (months) based on individual risk profile assessment. For high-risk children and adolescents' intervals less than 7 months, in case of low risk profile more than 7 months. In case of low-risk adults' profiles 9 months equal or more, and for high-risk adults' profiles less than 9 months.</p>	<p>Patient record, registration form to analyse risk management:</p>
<p>Secondary ROE-outcomes:</p> <p><u>Clinical Performance/decision making:</u> Number of patients per GDP with prescribed individual frequency of BWs (months). In case of high-risk children and adolescents' prescription frequencies of less than 24 months, and low risk profiles more than 36 months. In case of high-risk adults' prescription frequencies less than 36 months and low risk adults' prescription of more than 48 months.</p> <p>Number of patients per GDP with periodontal DPSI-score > 1, and prevalent caries, whom has been given feed back, information and preventive advice, registered in patient record or registration form.</p> <p><u>Efficacy data/cost-effectiveness scores:</u> Mean overall length in months of recall intervals per GDP over the past 3 yrs Mean total number of BW(s) and other radiographs over past 3 years Type of performer GDP/Oral hygienist/others (level of graduation - education) Total number of additional interventions performed during ROE (polishing, removal of calculus: coded as M50, M55).</p> <p><u>Professional attitudes and compliance:</u> At the start and at the end by questionnaire</p>	<p>Patient record, registration form, questionnaire to analyse additional performance and cost-analysis:</p>
<p>Primary MIM-outcome:</p> <p><u>Clinical performance/decision making:</u> Number of patients (between 18 –30 yr of age) with removed versus retained MIMs in accordance with CPG, or with indication for removal. Number of risk based assessment radiographs between 17- 30-yrs/per patient with risk based for assessment of prognosis MIM.</p>	<p>Patient record, registration form to analyse risk management</p>
<p>Secondary MIM-outcome:</p> <p><u>Professional attitudes/compliance and feedback:</u> Interviews of patients (17-30 years of age) to confirm risk based performance.</p>	<p>Questionnaire</p>
<p>These data will be compiled from questionnaires, patient vignettes, registration forms and from electronic patient records. All instruments were pre-tested in a pilot study. Measurements and analysis of pre-test data will take place before or during the intervention period (for retrospective data sampling), and after the intervention period (post-intervention data).</p>	

Timeframe of the study

It is planned to randomise 6 out of the initial recruited IQual groups, which have declared their willingness to participate in this study and to accept the random allocation to one of the two intervention groups. The base line data collection will take place at the beginning of the study during month 1-2. The intervention will start in months 2-3, and follow up data collection will be executed in months 8-10. The scheduled time for the trial is estimated on 7-10 months; assuming that each GDP will collect data from at least 20 regular attending patients by means of a structured developed registration form. See Appendix 1 for timeframe implementation study CPG on ROE and MIM.

Discussion

Little evidence was available on the estimates of the likely size of dental primary care ICCs and which prognostic factors influenced their magnitude. Based on research in this field (24-27), we assumed a substantial variation in primary dental care between fairly autonomously acting GDPs. Data extracted from primary health care (21-22), suggested that ICCs for patient outcomes in primary care were generally lower than 0.05. In reviews of this protocol, questions were raised about the power calculation. In particular, the expected effect size was seen as large and the applied intra cluster correlation as low. This would imply that the power calculated is too optimistic and that the study might be underpowered to detect meaningful change in professional behaviour.

Ethical and legal aspects

The study protocol was approved by the Ethics Committee of the Radboud University Nijmegen Medical Centre, previous to the start of the study in September 2006 (approval number xy). All patient data and other confidential information fall under dental confidentiality rules and are stored on a protected server of the Radboud University Nijmegen Medical Centre. Only members of the study team have access to the files.

Authors' contribution

All authors declare that they have no competing interests. DM, WvdS and MW performed the study and draft the manuscript. AP and RG participated in the study design. All authors have read and approved the final manuscript.

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Table 1. Overview of planned interventions in groups I and II.

Interventions for all IQualgroups		
Composition IQual group Introductory letter (individual) Delivery registration forms and questionnaires	Questionnaire GDPs 25 observations chair side	
Randomisation		
Interventions trial arms	ROE group I	MIM group II
Delivery CPG on ROE versus MIM by post	CPG ROE	CPG MIM
Education session IQual group	ROE education	MIM education
Online training website (individual feed back)	Access to ROE-based training	Access to MIM-based training
Reminder (flow chart), individual feed back record form Feed back by email	ROE- aspects Flow chart	MIM-aspects Flow chart
Registration in practice (25)	25 observations in practice chair side	25 observations in practice chair side
End trial	Questionnaire	Questionnaire

Table 2. Balanced incomplete block design

Intervention: Clinical Practice Guideline (CPG) on the management of routine oral examinations (ROE) and asymptomatic mandibular impacted third molars (MIM).

Intervention	CPG	
	ROE	MIM
Group I (ROE)	Intervention	Control
Group II (MIM)	Control	Intervention

Table 3.
Flow diagram of the progress through different steps of the trial

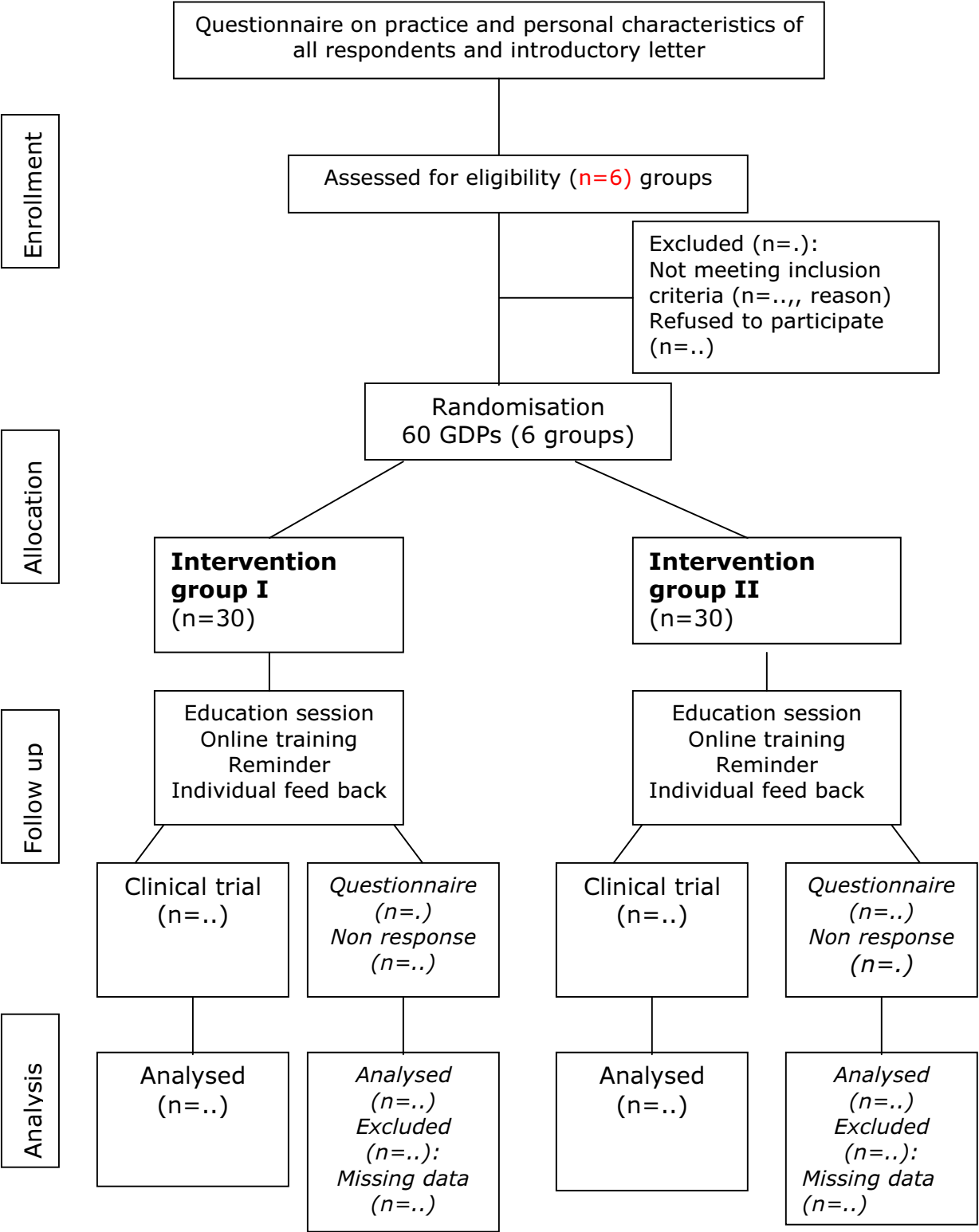


Figure 3

Figure 1:

Design: Timeframe Implementation study for CPGs on ROE and MIM

