

***Revised manuscript text:***

**Rationale, design and conduct of a primary dental care based intervention to improve professional performance on routine oral examinations and the management of asymptomatic impacted third**

**molars:** a cluster randomised controlled trial with an incomplete block design, a trial 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 decision making of fixed intervals. From a quality of care perspective as well, one can also question the effectiveness of the widespread prophylactic removal of mandibular impacted asymptomatic third molars (MIM) in adolescents and adults. It is as yet unclear how quality of oral care can be improved. Research data on effectiveness of interventions to promote continuing professional development for dentists are rare.

**Methods/Design:** This implementation study is a cluster randomised controlled trial with groups of GDPs as the unit of randomisation. The aim of the study 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 attend in monthly structured sessions scheduled for discussion on practice related topics.**

GDPs in both trial arms receive recent developed evidence-based CPG on ROE or MIM **respectively**. The implementation strategy consists of 1 interactive IQual circle 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. **A few weeks after the interactive meeting reminders (flow charts) will be send by mail.**

The main outcome measure for the ROE-study and control group is the use and appropriateness of individualised risk assessment in assigning recall intervals and for the MIM-study the use and appropriateness of individualised mandibular impacted third molar risk management.

Measurements (**pre-intervention** data collection) will take place in months 1-3, starting in September 2006. **Post-intervention** data collection will be performed after 9 months.

**Discussion:** 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. If the evaluation of this multifaceted implementation study reveals a shift in individual performance of GDPs in assessing risks for oral disease, further research questions and efforts to a risk-based professional education could be promoted.

**Rationale, design and conduct of a primary dental care based intervention to improve professional performance on routine oral examinations and the management of asymptomatic impacted third molars:** a cluster randomised controlled trial with an incomplete block design, a trial protocol.

## ***Background***

Routine oral examination (ROE) refers to periodic monitoring of the general and oral health status of patients. The purpose of a ROE is to prevent oral diseases, and to detect oral diseases at an early stage in such a way that only minimal interventions are required to arrest their progression. 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 in stead of systematic decision making of fixed intervals. In The Netherlands, about 80% of the population regularly visits the dentist (mostly twice a year) (1), so relatively healthy individuals are scheduled for routine oral screening in dental practice. In 2000, 50% of the GPs assigned all patients to visit dental practice twice a year (2) for routine oral screening, irrespective of individual risks for oral disease. The efficiency of this systematic monitoring can be disputed and an international debate is still ongoing (3-10). Recently, systematic reviews (11,12) and a clinical practice guideline (13) advocated an individualised risk based assessment strategy in the light of lack of good scientific evidence in this area. From a quality of care perspective as well, one can also question the effectiveness of the widespread prophylactic removal of impacted asymptomatic third molars in adolescents and adults (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 can be improved. Research data on effectiveness of interventions to promote continuing professional development for dentists are rare (17). A precious study showed that small group education improved knowledge in dentists, but not their clinical behaviour (20). We aim to demonstrate that a multifaceted strategy can enhance evidence-based dental practice. For this cluster randomised clinical trial, consensus based clinical practice guidelines (CPGs) on routine oral examinations (13) and on the management of asymptomatic mandibular impacted third molars (MIM) (20) was used for implementation in daily 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 mandibular impacted third molars (MIM) 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 asymptomatic impacted third molars (MIM) in daily dental practice is more effective and efficient compared to only dissemination of CPGs.

## ***Methods***

### **Study Design**

The study is a prospective cluster-randomised trial with incomplete block design. In one trial arm the intervention is focussed on individual recall decision-making performing ROEs. In the second arm the intervention is focussed on the monitoring and decision-making regarding the prophylactic removal versus retention of MIM. Groups of GDPs allocated to either of these arms act as each other's control group. To overcome confounding problems, as these will occur in both trial arms (Fig 1), groups of GDPs are randomised rather than individual GDPs. **Questioning potential risk of contamination due to overlapping clinical performance (behaviour) of both type of interventions can be neglected. After all, in the ROE-group the provided ROE-CPG only mentions the necessity of third molars screening in general as a final stage in the dentition development. In the MIM-group the provided MIM-CPG provides an extensively described decision-making algorithm i.e. how to deal with mandibular asymptomatic impacted third molars specifically.**

### **Recruitment of GDPs and inclusion/exclusion criteria**

Dental peer groups ("IQual-group"), each comprising at least participating GDPs, are the unit of randomisation. A dental peer 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 described.

### **GDPs inclusion criteria**

GDPs have to work in general dental practice for at least three days/week and should have practice experience for at least three years. They were eligible if their practice population was characterised by primary oral care patients, consisting of regular attendees, and patient recordkeeping was conducted electronically. GDPs had to give their informed consent to assess and evaluate electronically patient records. Patient data were collected anonymously.

### **Patient's inclusion criteria**

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

#### **ROE:**

All patients regularly visiting their dentist (at least once a year) over the past three years for ROEs will be included in the study.

#### **MIM:**

All patients regularly visiting their dentist (at least once a year) over the past three years for ROEs are included for the study and, in addition, have to be aged between 17 and 35 years, with disease-free impacted mandibular third molars in retention.

For both group of patients, it is important that they can be linked particular to the participating GDP, especially in practices with more than one GDP occupied.

### **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, respectively. The implementation strategy consists of 1 interactive IQual circle meeting of mostly 2-3 hours with a minimum of 8 GDPs each. These meetings intend to discuss the 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 on personal and group characteristics retrieved from pre-test questionnaire and 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 feed back to recommendations of CPG). These vignettes (risk profiles) are developed by means of structured consensus procedures (RAND/Delphi) with focus 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 upon the allocated trial arm participants are subjected to a set of planned interventions as described in Table 2.

## **Randomisation**

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

## **Outcome-parameters and instruments**

### **ROE-study**

Table 1 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 in assigning recall intervals (in months). The appropriateness will be assessed as follows:

- For children and adolescents (0 to 18 years): assessed as high risk profiles the recall interval should be assigned on less or equal than 7 months, for those defined within low risk profiles more than 7 months would be appropriate.
- For adults (18 years and older): assessed as high risk profiles the recall interval should be assigned on less than 9 months, for those within low risk profiles equal or more than 9 months.

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 (in months). The appropriateness will be assessed as follows:
  - For high caries risk children and adolescents (0 to 18 years) prescribed frequencies of less than 24 months are determined as appropriate, for low risk profiles a timeframe of 36 months or longer.
  - For high caries risk adults (18 years and older) prescribed BW-radiographs frequencies of less than 36 months are determined as appropriate, for low risk equal to 48 months or longer frequencies.
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:
  - For patients with one of the specified conditions the proportion per GDP, whom has been given 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 (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 hygienists/dental auxiliaries
  - Additional interventions per GDP (i.e. polishing stains/removing dental calculus) encompassed in 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 are collected with special registration forms, completed 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 given their informed consent to participate, GDPs were invited to fill out 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 (which will be individually applied in daily practice) will be used in the evaluation period.

Evaluation periods are planned immediately at the start (before randomisation of groups), and at the end of the trial after seven to nine months. Each GDP was 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 were collected from GDPs and co-workers (patients) to assess acceptance and applicability

## **Sample size**

**The primary outcome measures in this study are measured in 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 assumed 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 expected 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 used the ICC for clustering in IQUAL groups, because this was the unit of randomisation. We aimed 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 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 is not 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 resampling 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
<b>Primary ROE-outcomes:</b>	<b>Patient record, registration form to analyse risk management:</b>
<p><u>Clinical Performance/decision making:</u>            Number of patients per GDP with assigned recall interval (months) based on individual recall assessment of risk profile. For high risk children and adolescents less than 7 months, in case of low risk more than 7 months. For adults 9 months or more for low risk profiles, and less or equal than 9 months for high-risk profiles.</p>	
<b>Secondary ROE-outcomes:</b>	<b>Patient record, registration form, questionnaire to analyse additional performance and cost-analysis:</b>
<p><u>Clinical Performance/decision making:</u>            Number of patients per GDP with prescribed individual frequency of BWs (months). For high-risk children and adolescents less than 24 months frequency, in low risk profiles more than 36 months. For high-risk adults less than 36 months frequency versus low risk more than 48 months.</p> <p>Number of patients per GDP with periodontal DPSI-score &gt; 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>	
<b>Primary MIM-outcome:</b>	<b>Patient record, registration form to analyse risk management</b>
<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>	
<b>Secondary MIM-outcome:</b>	<b>Questionnaire</b>
<p><u>Professional attitudes/feedback:</u>            Interviews of patients (17-30 years of age) to confirm risk based performance.</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 (retrospective) 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.

## **Description of risks (participation in the study by patients)**

Serious risks or undesired effects of the recommendations of the CPGs are not known. There are no specific risks for patients related to the study.

## **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. Balanced incomplete block design**

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

<b>Intervention</b>	<b>CPG</b>	
	<b>ROE</b>	<b>MIM</b>
Group I (ROE)	Intervention	Control
Group II (MIM)	Control	Intervention

**Table 2. Overview of planned interventions in groups I and II.**

<b>Interventions for all IQualgroups</b>		
Composition IQual group Introductory letter (individual) Delivery registration forms and questionnaires	Questionnaire GDPs 25 observations chair side	
<b>Randomisation</b>		
<b>Interventions trial arms</b>	<b>ROE group I</b>	<b>MIM group II</b>
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 3.**  
**Flow diagram of the progress through different steps of the trial**

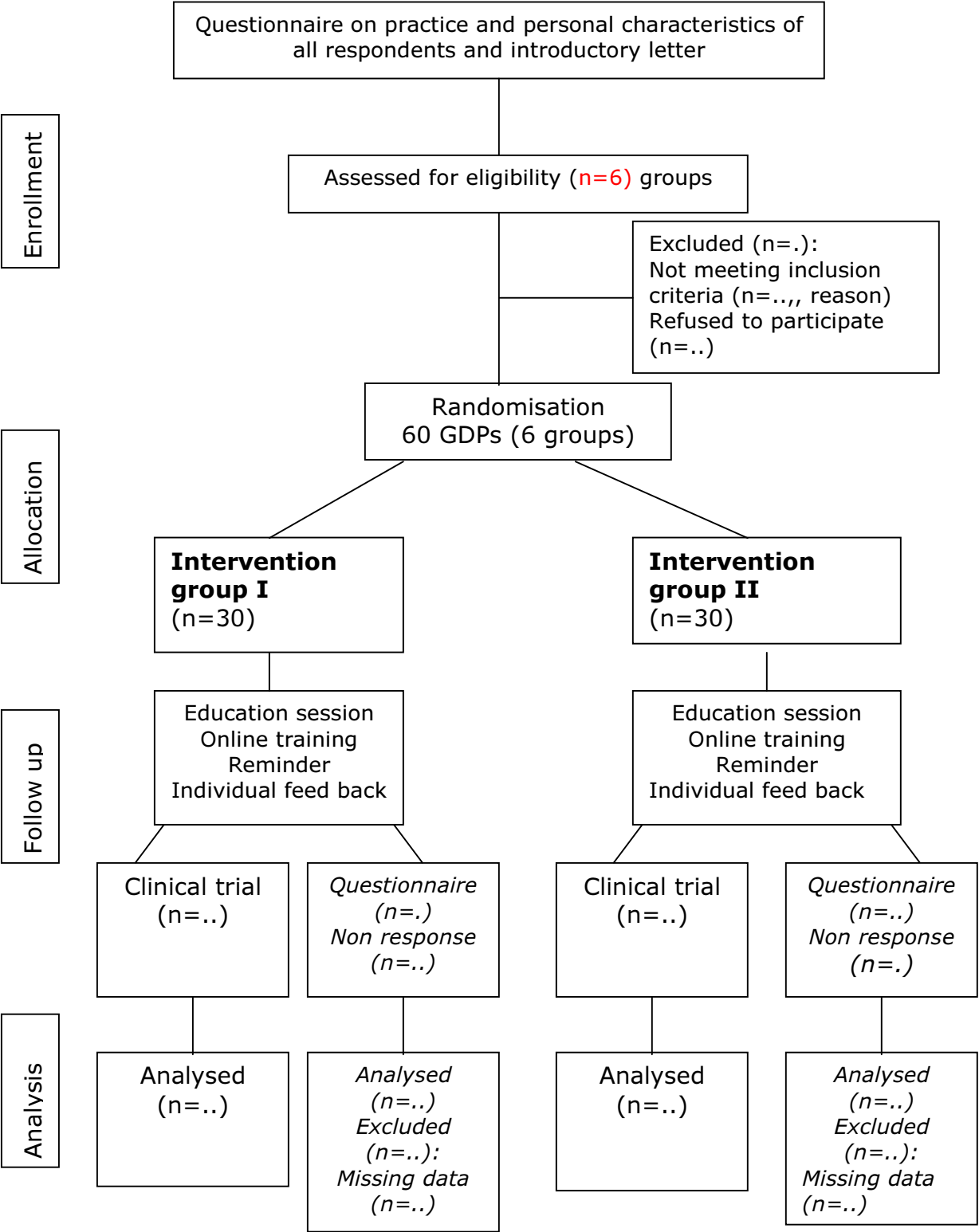


Figure 3

**Figure 1:**

**Design: Timeframe Implementation study for CPGs on ROE and MIM**

