

[Start](#) | [Browse by Day](#) | [Author Index](#) | [Keyword Index](#)

192 Randomized Clinical Trial in the Field–Recruitment and Practitioners Profil

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Location: Poster Hall (Finlandia Hall)

Presentation Type: Poster Session

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Objectives: EU-regulations regarding Conformité Européenne for medical products require clinical trials. At present randomized clinical trials (RCT) run at universities, but to address these legislative recommendations, the number of clinical studies has to increase steadily. An effective approach is to involve more private practices in study designs. Cluster design studies -biased by treatment and frequency- and RCT studies -limited by workload for treatment and examination - an RCT in the field was introduced and evaluated with the aim of reducing selection-bias of performing practitioners networks (double-stage-randomisation of location and GPs). As a side effect, trials will reflect more daily treatment routine in general dental practice (CONSORT criteria). This research focused on analyzing response and practitioners' profile.

Methods: A study proposal (N=3194) was sent to randomly selected dental offices in selected German cities (50-250T inhabitants). Mailing additional offices continued until 11 dentists per city declared participation. Briefing lectures informed the dentists about design, methods, treatment procedures and calibration according to GCP/GMP. A questionnaire adjusting location and partnership in the practice, year of examination, dental practice age, specialization, number of patients with statutory health insurance and private patients has been done.

Results: Only 237 (7.4%) declared, 160 (5.0%) affirmed definitely. The urban located offices existed in the mean 20.6yrs, 17.3yrs in the outskirts of cities and 20.1yrs for rural located offices. 53.5% has no partnership, 36.4% had two partners and 9.2% more than three partners. The majority of general dentists were specialized. Privately insured patients ($p<.05$) were more frequent in specialized practices.

Conclusions: Response in recruitment strategy was disappointing (Lasagna's law). Regional differences, dentist's specialization and differences in patients health safeguarding have to consider running field RCTs.

Keywords: Epidemiology and RCT