

SWAT 206: Could dental hygienists or dental therapists, instead of a dentist, acting as a principal investigator (PI) lead to more efficient delivery of a clinical trial at the site level?

Objective of this SWAT

To compare recruitment rates, retention rates and process factors between a dental hygienist or dental therapist (DH/DT), versus a dentist acting as principal investigator (PI) on a clinical trial.

Study area: Recruitment, Retention, Data Quality

Sample type: Healthcare Professionals

Estimated funding level needed: Low

Background

As part of The James Lind Alliance Priority Setting Partnership PRioRiTY I & II studies, the top ten most important questions in trial recruitment and retention were identified. A key focus was how trials can be designed to minimise staff burden and the barriers and enablers to participation in randomised trials for other clinicians and healthcare professionals. In primary care dental research, the site dentist has almost always been the 'PI' or 'lead', and although the dentist is the lead in a dental team, they are also the most expensive and often the busiest. There is considerable scope for other members of the dental team (namely dental hygienist or dental therapist) to act as the PI, where the trial is within their scope of practice.

This SWAT will be non-randomised because not all practices have a DH/DT who could take on the role of a trial PI. Practices will self-select into either dentist or DH/DT lead sites. Recruitment rates, retention rates and process factors will be evaluated at each site and compared between sites with the two different types of PI. Qualitative research will be used to attempt to explain any differences observed.

The SWAT will be embedded in the ENHANCE-D (Enhancing Dental Advice) trial (ISRCTN13158982), which is a pragmatic, multi-centre, definitive, open-label, 3-arm, parallel group, individually randomised superiority trial (<https://research.ncl.ac.uk/enhance-d>).

Interventions and comparators

Intervention 1: Dentist acting as PI

Intervention 2: Dental hygienist or dental therapist acting as PI

Index Type: PI role

Method for allocating to intervention or comparator

Self-selected

Outcome measures

Primary: Efficiency of delivery of the trial at the site level (measured via recruitment rates, retention rates and process factors).

Secondary:

Analysis plans

To be developed.

Possible problems in implementing this SWAT

This SWAT relies on some dental practice sites having a DH/DT who is willing and able to be the local PI and there is a risk that most practices in the host trial will have a dentist as local PI. The sites will self-select their type of PI, rather than being randomised for this, which means that factors other than the type of PI might influence the findings.

References

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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Revisions made by:

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