

SWAT 11: Monitoring consent forms by Skype videoconferences

Objective of this SWAT

To assess the accuracy of information conveyed to the trial coordinating centre via Skype-based telemonitoring compared to in-person site visits.

Study area: Monitoring; Data quality.

Sample type: Trial team.

Estimated funding level needed: Very low.

Background

Source data verification is a requirement for many randomised trials and can involve resource intensive site visits in multi-centre trials. New technologies such as Skype videoconferences might provide a low-cost alternative to this, if documents such as patient consent forms could be shown to the central trial team during the videoconference.

Interventions and comparators

Intervention 1: Periodic Skype videoconferences with staff at each site during which patient consent forms would be shown to the central trial team.

Intervention 2: In-person site visits by the central trial team to conduct 100% source data verification of patient consent forms (blinded to any findings from the Skype videoconferences).

Index Type: Method of Monitoring, Visit

Method for allocating to intervention or comparator

All sites (or a sample) would receive both interventions.

Outcome measures

Primary outcomes: Number of consent errors with Skype videoconferencing, compared to the 'gold standard' source data verification through the site visit.

Secondary outcomes: Costs of monitoring.

Analysis plans

Simple proportions will be calculated based on the number of errors. Subgroup analyses might be performed based on site characteristics to investigate whether errors rates differ between different types of site.

Possible problems in implementing this SWAT

(1) Verification of consent forms by Skype videoconferencing might affect the on-site source data verification, which could be explored through randomising whether the Skype verification is before or after the site visit. (2) The central trial team and the site staff might become frustrated by having to undertake verification of all consent forms by both methods.

Person to show as the source of this idea: Peter J. Kelly.

Contact email address: PJKELLY@PARTNERS.ORG.

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