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Randomized controlled trials: who fails run-in?

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Background

Early identification of enrollees at risk of poor adherence and run-in failure (RIF) may present opportunities to increase trial efficiency and generalizability.

Methods

We conducted a factorial-design randomized, controlled trial of calcium and vitamin D to prevent colorectal adenoma recurrence. At the enrolment interview, study coordinators at 11 centers collected demographic and medical information and participants' beliefs about the study tablets. Participants also completed two self-administered questionnaires (SAQ) before a three-month single-blinded placebo run-in. Eligible participants were then randomized to calcium, vitamin D, both or neither; women electing to take calcium were randomized to vitamin D or placebo. *A priori*, we considered three subgroups: men (N=1606) and women (N=301) in the full factorial randomization and women in the 2-arm randomization (N=666).

Results

Overall, 314 of 2,573 (12%) enrollees potentially eligible for randomization failed run-in due to poor adherence (took <80% tablets) or refusal to participate. In multivariable models in the largest subgroup (males), RIF was associated with younger age (adjusted odds ratio per 5 years 0.85; 95% CI 0.76-0.96), single marital status (1.67; 1.12-2.49), any missing data on the SAQs (2.05; 1.46-2.86) study center ($p<0.0001$) and perceived toxicity report (12.86; 5.41-30.56). Across all three subgroups, the latter three factors were most consistently associated with RIF but other factors are described which vary by subgroup.

Conclusions

The most consistent predictors of RIF were perceived toxicities, missing data on self-administered questionnaires, and study center. The latter two findings relate to study coordinator oversight, and present potential opportunities to improve adherence during run-in.

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