What Was the Primary Outcome?

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We read the paper by Sattler and coworkers with great interest. The authors are to be commended for undertaking a physical therapy trial in the acute postoperative setting after total knee replacement (TKR). They are also to be commended for the prospective registration of their trial (1), as is encouraged for rehabilitation trials (2). However, the authors´ reporting of outcomes makes the interpretation of the findings difficult.

A “primary outcome” measure is the prespecified outcome considered to be of greatest importance to relevant stakeholders (3), and it is generally the outcome for which efficacy is primarily assessed. There seems to be some confusion as to what was the primary outcome in the trial by Sattler et al. The trial registry (1) lists three prespecified primary outcomes in the following order: 10-meter walk test [primary outcome 1], 6-minute walk test [primary outcome 2], and EuroQol 5 [primary outcome 3]) – all collected 2 days, 2 weeks, and 4 months after TKR.

In the published report, however, only the 6-minute walk test is defined as the primary outcome, without an indication of which timepoint (2 days, 2 weeks, or 4 months) was the prespecified timepoint of primary interest. A clinically meaningful between-group difference in walking distance, as assessed by the 6-minute walk test, was observed at the 2-day follow-up only. Could the authors please clarify this primary-outcome confusion?
References


Conflict of Interest: None Declared