

Structured Abstract for Scholarly Projects Reporting Original Data from Clinical Setting:

Reports of original data should include an abstract of no more than 350 words using the headings listed below. For brevity, parts of the abstract may be written as phrases rather than complete sentences. Each section should include the following content:

Project title: Ideally short and direct

Author names: student and mentor

Importance: The abstract should begin with a sentence or 2 explaining the clinical (or other) importance of the study question.

Objective: State the precise objective or study question addressed in the report (e.g., "To determine whether..."). If more than 1 objective is addressed, the main objective should be indicated, and only key secondary objectives stated. If an a priori hypothesis was tested, it should be stated.

Design: Describe the basic design of the study and include the specific study type (e.g., randomized clinical trial, cohort, cross-sectional, case-control, case series, survey, before-after). State the years of the study and the duration of follow-up. As relevant, indicate whether observers were blinded to patient groupings, particularly for subjective measurements.

Setting: Describe the study setting to assist readers to determine the applicability of the report to other circumstances, for example, inpatient, ICU, population-based, primary care center(s), etc.

Participants: State the clinical disorders, important eligibility criteria, and key sociodemographic features of patients (or other study participants). The numbers of eligible participants and how they were selected should be provided, including the number approached but who refused or were excluded. For selection procedures, these terms should be used, if appropriate: random sample (where random refers to a formal, randomized selection in which all eligible individuals have a fixed and usually equal chance of selection); population-based sample; referred sample; consecutive sample; volunteer sample; convenience sample. If matching is used for comparison groups, characteristics that are matched should be specified. In follow-up studies, the proportion of participants who completed the study must be indicated.

Intervention(s) (for clinical trials) or Exposure(s) (for observational studies): The essential features of any interventions, or exposures, should be described, including their method and duration. The intervention, or exposure, should be named by its most common clinical name, and nonproprietary drug names should be used.

Main Outcome(s) and Measure(s): Indicate the primary study outcome measurement(s) as planned before data collection began. If the manuscript does not report the main planned outcomes of a study, this fact should be stated, and the reason indicated. State clearly if the hypothesis being tested was formulated during or after data collection. Explain outcomes or measurements unfamiliar to a general medical readership.

Results: Summary demographic information (e.g., characteristics such as sex and age) and the number of study participants should be reported in the first sentence of the Results paragraph. The main outcomes of the study should be reported and quantified, including final included/analyzed sample. When possible, present numerical results (e.g., absolute numbers and/or rates) with appropriate indicators of uncertainty, such as confidence intervals. Use means and standard deviations (SDs) for normally distributed data and medians and ranges or interquartile ranges (IQRs) for data that are not normally distributed. Avoid solely reporting the results of statistical hypothesis testing, such as P values, which fail to convey important quantitative information. For most studies, P values should follow the reporting of comparisons of absolute numbers or rates and measures of uncertainty (e.g., 0.8%, 95% CI -0.2% to 1.8%; $P = .13$). *P values should never be presented alone without the data that are being compared.* See also Reporting Standards and Data Presentation. Measures of relative risk also may be reported (e.g., relative risk, hazard ratios) and should include confidence intervals. Studies of screening and diagnostic tests should report sensitivity, specificity, and likelihood ratio. If predictive value or accuracy is reported, prevalence or pretest likelihood should be given as well. All randomized clinical trials should include the results of intention-to-treat analysis as well. In intervention studies, the number of patients withdrawn because of adverse effects should be given. Approaches such as number needed to treat to achieve a unit of benefit may be included when appropriate. All surveys should include response/participation rates.

Conclusions and Relevance: Provide only conclusions of the study that are directly supported by the results. Give equal emphasis to positive and negative findings of equal scientific merit. Also, provide a statement of relevance indicating implications for clinical practice or health policy, avoiding speculation and overgeneralization. The relevance statement may also indicate whether additional study is required before the information should be used in clinical settings.

Effect of Electronic Symptom Monitoring on Patient-Reported Outcomes Among Patients With Metastatic Cancer

A Randomized Clinical Trial

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IMPORTANCE Electronic systems that facilitate patient-reported outcome (PRO) surveys for patients with cancer may detect symptoms early and prompt clinicians to intervene.

OBJECTIVE To evaluate whether electronic symptom monitoring during cancer treatment confers benefits on quality-of-life outcomes.

DESIGN, SETTING, AND PARTICIPANTS Report of secondary outcomes from the PRO-TECT (Alliance AFT-39) cluster randomized trial in 52 US community oncology practices randomized to electronic symptom monitoring with PRO surveys or usual care. Between October 2017 and March 2020, 1191 adults being treated for metastatic cancer were enrolled, with last follow-up on May 17, 2021.

INTERVENTIONS In the PRO group, participants (n = 593) were asked to complete weekly surveys via an internet-based or automated telephone system for up to 1 year. Severe or worsening symptoms triggered care team alerts. The control group (n = 598) received usual care.

MAIN OUTCOMES AND MEASURES The 3 prespecified secondary outcomes were physical function, symptom control, and health-related quality of life (HRQOL) at 3 months, measured by the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (QLQ-C30; range, 0-100 points; minimum clinically important difference [MCID], 2-7 for physical function; no MCID defined for symptom control or HRQOL). Results on the primary outcome, overall survival, are not yet available.

RESULTS Among 52 practices, 1191 patients were included (mean age, 62.2 years; 694 [58.3%] women); 1066 (89.5%) completed 3-month follow-up. Compared with usual care, mean changes on the QLQ-C30 from baseline to 3 months were significantly improved in the PRO group for physical function (PRO, from 74.27 to 75.81 points; control, from 73.54 to 72.61 points; mean difference, 2.47 [95% CI, 0.41-4.53]; $P = .02$), symptom control (PRO, from 77.67 to 80.03 points; control, from 76.75 to 76.55 points; mean difference, 2.56 [95% CI, 0.95-4.17]; $P = .002$), and HRQOL (PRO, from 78.11 to 80.03 points; control, from 77.00 to 76.50 points; mean difference, 2.43 [95% CI, 0.90-3.96]; $P = .002$). Patients in the PRO group had significantly greater odds of experiencing clinically meaningful benefits vs usual care for physical function (7.7% more with improvements of ≥ 5 points and 6.1% fewer with worsening of ≥ 5 points; odds ratio [OR], 1.35 [95% CI, 1.08-1.70]; $P = .009$), symptom control (8.6% and 7.5%, respectively; OR, 1.50 [95% CI, 1.15-1.95]; $P = .003$), and HRQOL (8.5% and 4.9%, respectively; OR, 1.41 [95% CI, 1.10-1.81]; $P = .006$).

CONCLUSIONS AND RELEVANCE In this report of secondary outcomes from a randomized clinical trial of adults receiving cancer treatment, use of weekly electronic PRO surveys to monitor symptoms, compared with usual care, resulted in statistically significant improvements in physical function, symptom control, and HRQOL at 3 months, with mean improvements of approximately 2.5 points on a 0- to 100-point scale. These findings should be interpreted provisionally pending results of the primary outcome of overall survival.

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