Abstract

Title: A review of goal attainment scaling as an outcome in clinical trials.

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Aims

Capturing the spectrum of personally meaningful changes with standardized outcomes in clinical trials is challenging. Goal attainment scaling (GAS) is an individualized patient-reported outcome that quantifies the effects of an intervention based on personal goals. It is well-suited to evaluating interventions for conditions with high heterogeneity in symptoms and progression. Our aim was to review how GAS is used in clinical trials.

Methods

We searched ClinicalTrials.gov with the terms "goal attainment scale" and "goal attainment scaling", without any additional restrictions. Each trial was reviewed by the authors. Areas of study (disease or condition) were consolidated with umbrella terms, allowing consistent naming. Studies were summarized based on type (interventional/observational) and trial phase (II, III, etc.).

Results

Of 162 trials identified, we excluded 3 in GAS was not an outcome. Start dates ranged from 2004-11-01 to 2021-10-01, with most (n=103, 65%) starting in 2015 or later. Nearly half (71, 45%) of the trials were ongoing (pre-recruitment, recruiting or active). The majority were interventional (143, 90%); 16 (10%) were observational studies. Of the 30 interventional trials with phases listed, most were phase III (12, 40%), 8 (27%) were phase II and 9 (30%) were phase IV; one trial was a combination phase II and III trial.

GAS was used as a primary outcome in 60 (38%) trials, as a secondary outcome in 89 (56%) trials, and an 'other' outcome in 10 (6%) trials. In 6 (4%) trials, GAS was also part of the intervention.

The most common applications of GAS were in spasticity (31, 19% of trials), cerebral palsy (25, 16%), and stroke (17, 11%). Several novel uses of GAS were identified: 35 conditions were studies in just one trial, including hemophilia, Down

syndrome and epilepsy.

Conclusions

In recent years, there has been an increase in the number of trials using GAS across multiple disciplines, primarily in interventional studies as a secondary outcome. This shows a growing enthusiasm for GAS as a patient-reported outcome in clinical trials.