

Obese patients underrepresented in cancer clinical trials

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Obesity is a risk factor for a number of cancer types and can influence cancer treatment outcomes. In 2014, cancer types associated with being overweight or obese represented about 40 percent of all cancers diagnosed in the United States.

But a new review by Boston University School of Public Health (BUSPH) researchers found that less than one-fifth of participants in cancer-related clinical [trials](#) are obese.

The study was published in *Annals of Oncology*.

"Randomized trials are essential to assess the efficacy and safety of new cancer treatments," says senior author Ludovic Trinquart, assistant professor of biostatistics at BUSPH. "However, randomized trials may lack representation of the true clinical populations that will receive the treatment."

Between 2013 and 2014, 35 percent of men and 40 percent of women fell under the BMI "obese" category; since then, the global prevalence of [obesity](#) has increased dramatically. Obesity may be associated with an increased risk of progression, recurrence, and death for specific [cancer types](#).

"If [obese people](#) are poorly represented, cancer randomized controlled trials (RCTs) may fail to provide adequate information to judge the effect of treatments and dosing in real world settings," the authors wrote.

"Our objective was to assess the reporting of information about eligibility and enrollment of obese participants in obesity-related cancer RCTs."

The researchers reviewed 76 clinical trials between the years of 2013 and 2016. For each trial, they assessed the proportion of obese participants, if the eligibility criteria limited the enrollment of obese participants, and whether an analysis according to [obesity status](#) was conducted. The researchers also contacted the authors of the trials and asked for more information about the eligibility of obese participants and the proportion of obese participants.

From data obtained from 22 trials, the researchers determined the median proportion of obese participants to be just 18 percent. While obesity was not listed as an exclusion criterion for any of the trials, whether obese participants were eligible to participate or not was unclear in 93 percent of trials. The researchers also found that 95 percent of trials did not initially report on the proportion of obese participants enrolled.

The authors cautioned that underrepresentation of [obese patients](#) in obesity-related cancer randomized controlled trials may affect generalizability of results and treatment outcomes.

"The lack of information regarding enrollment of obese participants stands in sharp contrast with the expanding real-world concern of obesity in cancer and ongoing reflections about improving the assessment drugs' safety and efficacy in patients who will ultimately receive them," they wrote. "Given the role of obesity in shaping [cancer](#) risks and outcomes, our results highlight the critical need to improve the reporting of obesity status information."

BUSPH alumna Ella Pestine, now a senior research assistant at Harvard

Pilgrim Health Care Institute, was lead author on the study. Andrew Stokes, assistant professor of global health at BUSPH, was co-author.

More information: E Pestine et al, Representation of Obese Participants in Obesity-Related Cancer Randomized Trials, *Annals of Oncology* (2018). [DOI: 10.1093/annonc/mdy138](https://doi.org/10.1093/annonc/mdy138)

Provided by Boston University School of Medicine

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