INTRODUCTION:
In 2011, there were over 240,000 new cases of prostate cancer (CaP) in the United States. Men currently have a 1 in 6 chance of developing CaP in their lifetime. Increased circulating concentrations of insulin-like growth factor I (IGF-I) in humans is consistently reported to be associated with an increased risk of CaP. Dietary factors that can alter the concentrations of IGF-I, such as the green tea polyphenol (GT) antioxidants, may be one potential mechanism to reduce CaP risk.

SPECIFIC AIM:
Determine if green tea (GT) supplementation lowers circulating IGF-I in men at risk for prostate cancer.
• Hypothesis: We hypothesize GT supplementation will lower IGF-I in men at risk for prostate cancer (CaP) versus placebo (PP).

METHODS:
We conducted a sub-analysis of plasma (n=71) and serum (n=3) samples from a recent randomized, double-blind, placebo-controlled trial examining GT and fish oil (FO) supplementation in men at risk for CaP. Men received either GT and FO placebo; FO and GT placebo; GT and FO (GTFO); or double placebo (PP). Average supplementation was 15 weeks.
IGF-I was measured before and after treatment using commercially available radioimmunoassay (RIA) kits. Two separate analyses were conducted:
The first analysis incorporated 2 treatment arms: GT (n=13) versus PP (n=24)
The second analysis combined treatment arms: GT+GTFO (n=26) versus PP+FO (n=48)
Pre-post differences were analyzed in STATA for all four treatment arms. T-tests were run comparing absolute changes in IGF-I between GT and PP groups. For the second analysis, GT+GTFO was compared to PP+FO. FO was considered to be an additional placebo.

RESULTS:
1. First analysis (n=37):
GT supplementation significantly lowered IGF-I compared to PP (p=0.01). Two-sided significance was also obtained when comparing absolute change between the two groups (p=0.02).

2. Second analysis (n=74):
After combining treatment arms, and considering the FO to be an additional placebo, the effect of GT on IGF-I levels was still significant compared to placebo (p=0.0495, one-sided).

SUMMARY AND CONCLUSIONS:
This is the first study demonstrating that GT supplementation significantly lowers IGF-I in men at risk for CaP.
This is also the first trial in humans that has demonstrated a significant lowering effect of GT versus placebo on IGF-I. To date, only one other trial has compared the effect of GT versus placebo on IGF-I, but that study did not demonstrate a significant effect.

Our most significant results were found in the absence of fish oil supplementation (GT vs PP). To see if GT and GTFO groups could be considered equivalent for the combined analysis we compared post-treatment values (p=0.14) and absolute post-pre changes (p=0.14). In both cases, they were not significantly different. The same tests were performed to compare the FO and PP groups.
Neither post-treatment IGF-I (p=0.46) nor absolute post-pre changes (p=0.74) were different.
A small number of published reports suggest that FO may raise IGF-I. We may speculate that, in the combined analysis, FO may have worked against the capacity of GT to lower IGF-I. This may explain why the GTFO group had a significantly lower proportion of decreases in IGF-I compared to the GT group (p=0.047; Fischer’s exact test).
Reduced levels of IGF-I are associated with decreased risk of CaP. This study shows that GT may reduce IGF-I in men at risk for CaP, which may, in turn, reduce their risk of subsequently developing CaP.