**BIFIDOBACTERIUM ANIMALIS SSP. LACTIS 420 WITH OR WITHOUT LITESSE® ULTRA CONTROLS BODY FAT MASS AND WAIST CIRCUMFERENCE IN OVERWEIGHT AND OBESITY – RANDOMIZED, DOUBLE-BLIND, MULTICENTER CLINICAL STUDY**

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**Introduction:**
The composition of gut microbiota is interlinked with energy balance, but causal evidence between its modulation and body fat mass is still very scarce. Despite intense research on probiotics, only a handful of human studies have shown benefits on improving glucose metabolism, and only tentative proof has been gathered so far for an effect on weight control. We investigated the effects of probiotic Bifidobacterium animalis ssp. lactis 420 (B420) and a dietary fiber, Litesse® Ultra polydextrose (LU), on body fat mass and other parameters related to obesity.  

**Methods:**
A total of 225 healthy participants were randomized into four groups for 6 mo of treatment: 1) Placebo; 2) LU, 12 g/d; 3) B420, 1010 CFU/d; 4) LU+B420, 12 g + 1010 CFU/d. Participants maintained their habitual diet and exercise routines during the study. Body composition using Dual-Energy X-ray Absorptiometry (DEXA), anthropometric measurements, and blood samples were taken at 0, 2, 4 and 6 months, as well as one month after end of treatment. Blood samples were analyzed for markers of energy metabolism and inflammation.

**Results:**
Due to the long intervention period and several protocol violations there were marked differences in the results of Intention-To-Treat (n = 209) and Per Protocol (n = 134) groups. The Per Protocol analysis included participants who completed the intervention period with at least 80% product compliance and did not use systemic antimicrobials during the intervention, as was pre-defined. There were no significant differences in body fat mass in the Intention-To-Treat population. However, LU+B420 and B420 seemed to improve weight management in the Per Protocol population. For change in body fat mass, LU+B420 showed a -4.6% (-1.4 kg) difference to Placebo (P=0.02), whereas LU alone had no effect, and the overall ANCOVA was non-significant (P=0.095). The factorial analysis for total fat mass was significant for B420 (P = 0.002 vs. Placebo). The effects on body fat mass were most pronounced in the abdominal region, reflected by a reduction in waist circumference in the LU+B420 group -2.7% (-2.6 cm), P = 0.047 vs. Placebo, ANCOVA P = 0.10. In the factorial analysis, reduction in waist circumference was significant for B420 (P= 0.004 vs. Placebo). However changes in zonulin, a potential marker of intestinal permeability, and high sensitivity C-reactive protein (hsCRP) from baseline to 6 months were associated with corresponding changes in trunk fat mass in the total Per Protocol population. On a group-wise level this association was significant only in the LU+B420 group.

**Discussion:**
This is to date the largest and most strictly controlled study to show that a probiotic with or without a dietary fiber controls body fat mass in healthy adults. B420 and LU+B420 showed benefits for controlling body fat mass and waist circumference, whereas LU had no effect. The reduction in trunk fat mass was associated with lower levels of zonulin and hsCRP suggesting that B420 and LU+B420 could potentially influence adipose tissue metabolism by improving gut barrier and inflammatory tone. (Clinicaltrials.gov NCT01978691)

**Keywords:** Probiotics, Bifidobacterium lactis B420, Polydextrose, Obesity, Weight management
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