RESEARCH PROGRESS REPORT SUMMARY

Grant 02723: Scientific and Clinical Assessment of Fecal Microbiota Transplant in Obese Dogs: SLIM Study

Principal Investigator: Jenessa Winston, DVM, PhD

Research Institution: The Ohio State University

Grant Amount: $94,989

Start Date: 6/1/2020 **End Date:** 5/31/2023

Progress Report: End-Year 2

Report Due: 5/31/2022 **Report Received:** 6/11/2022

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Original Project Description:

Obesity is a growing epidemic in companion animals. Obesity results from a prolonged positive energy balance leading to excessive fat accumulation, which promotes dysregulation of metabolic, hormonal, and inflammatory responses. Ultimately these changes lead to physical impairment, comorbidities, and reduced quality of life. Evidence is mounting that the intestinal microbiota (collection of microorganisms that live in the intestines) contributes to obesity, and rational manipulation of this ecosystem may confer a health benefit. This study will provide a comprehensive scientific and clinical assessment of the efficacy of fecal microbiota transplantation (FMT) as an adjunctive therapy for canine obesity management. The investigators hypothesize that FMT (the transfer of feces from a healthy, lean donor dog into an obese dog) will amplify weight loss in obese dogs compared to the use of standard dietary obesity management. A randomized, placebo controlled clinical trial in client-owned obese dogs consisting of three groups: diet alone, diet + FMT, diet + placebo will provide data on weight loss and characterize the intestinal microbiota and metabolic function. Success of this study will benefit obese dogs by providing a microbial intervention to augment current strategies for canine obesity management aimed at promoting weight loss, normalizing metabolic status, and improving quality of life.

Publications:

Standardized Preparation of Fecal Microbiota Transplant Capsules for Companion Animals. Randolph, N., Klein, H., Salerno, M., Horne, R., and J. Winston. Target Journal: PloS One Protocols. We have added in 16S amplicon microbiome analysis to this manuscript to ensure that fecal processing is not

significantly impacting the microbiome. The manuscript is currently in preparation with anticipated submission in Summer 2022.

Presentations:

The PI (Dr. Winston) was invited to give several veterinary podcasts, related to fecal microbiota transplantation and during these the SLIM study was discussed.
• Morris Animal Foundation's Fresh Scoop podcast show titled "The Amazing Science of Fecal Microbiota Transplantation". Aired on January 13, 2022.
• Fully Vetted podcast show titled "The Power of Poop: Fecal Transplants for Treating Disease". Aired on January 3, 2022.

ACVIM Forum 2022 invited oral research abstract presentation titled: "Standardized preparation of canine fecal transplant material does not alter microbial community structure". Randolph, N., Klein, H., Salerno, M., and J. Winston.
• This oral presentation provides evidence that our standardized preparation of canine FMT capsules utilized in the SLIM study did not significantly alter the microbial community structure. This data will be presented by a fourth-year veterinary student who assisted with this project (M. Salerno). Due to the ACVIM Forum requirements, we held on submitting this data for publication until after the presentation (see above publication section).

Report to Grant Sponsor from Investigator:

To date, we have screened (comprehensive physical examinations, bloodwork, and fecal analysis) 51 dogs for the SLIM study. Of these, 31 have met the inclusion criteria and were enrolled. Of these enrolled dogs, 23 dogs have completed the 24-week clinical trial and 2 dogs are currently enrolled (see Figure 1). Unfortunately, 6 dogs were removed from the study early with the most common reason related to administration of antimicrobials needed for underlying health conditions including dog bite wounds, urinary tract infections, and surgical procedures. Based on recalculating our power analysis for sample size estimation, out current samples size (n=25) is sufficient to find a significant difference in weight loss between the treatment groups. Therefore, we are not planning to recruit any additional dogs for the SLIM study. All currently enrolled dogs will finish the study in October 2022 and then we can enter the analysis phase of this clinical trial.

The most rewarding part of this clinical trial is that all dogs are achieving their weight loss goals, despite their treatment group. Our patients' owners are thrilled with how their pets are progressing in their weight loss goals and are greatly appreciative for the improvement in their pets' quality of life since completing the SLIM study. For example, over the 24-week SLIM study, Pax's achieved a total weight loss of 23% of his body weight (see Figure 2). His body condition score (BCS) improved from 8/9 to 5/9 during the SLIM study. His owners' report a marked improvement in his energy and actively

levels since completing the SLIM study. Our institution continues posting social media stories about our patients' weight loss journeys.