

Commentary on Alternative Therapies and Life Style Interventions for Obese Individuals with Type 2 Diabetes

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With obesity worldwide reaching pandemic levels (recent global research indicates over 2 billion individuals either obese or overweight...one-third of the world population), it has pervaded countries with greatly different cultures and nutritional habits. Many different interventions have been offered and researched in the past ten years with some intervention approaches being significantly better than others. As practitioners look for alternative therapies for patients who are obese with Type 2 Diabetes and view best practice approaches available, the current controversy using the traditional Metformin and GLP 1 Receptor Agonists (Byetta, Bydureon, Tanzaum, Trulicity and Victoza) has caused many practitioners to consider alternative therapies. Additionally, in the US alone, one-third of the 323 million population (2016) is classified as diabetic or pre-diabetic by the CDC (US Centers for Disease Control and Prevention).

During recent visits with various healthcare practitioners as part of the 2017 America's Pharmacy Tour (www.AskDrS.org) the emergence and embrace of dietary supplement protein rich meal replacements (PRMR's) as alternative therapy is a demonstrated growing trend. One such product is diabetic friendly Almased®, first marketed in Germany some thirty years ago. Created by the holistic pharmacist Hubertus Trouille it now also experiences wide spread distribution in the United States.

First reports regarding research into the use of PRMR's for obesity was presented at the 2012 American Diabetes Association (www.diabetes.org) annual meeting in Philadelphia by Stephan Martin, MD, from the West German Center for Diabetes and Health in Dusseldorf, Germany. This 12 week pilot study demonstrated that an Almased® diet regimen worked well with patients who were using an average 147 Units of insulin per day. After just one week insulin demand was reduced to 65 units/day. Blood level A1C and body weight decreased significantly at all time points. During week 1 of the pilot trial, the three main meals were replaced with 50 gram servings. In weeks 2 - 4, breakfast and dinner were replaced and in weeks 5 - 12 only dinner was replaced. At a 1.5 year follow-up insulin requirement and weight remained significantly lower than baselines for those who continued use after initial compliance of the recommended metabolism adjustment approach and then either one meal daily or sporadically (Kempf *et al.*, 2013; <http://dx.doi.org/10.1111/jhn.12145>).

Use of this PRMR Almased® alternative therapy approach confirmed that the use of Almased® continuously in their life supported their weight loss and diabetes challenges. Without continuous use, however, the daily insulin demand, A1C and body weight increased again. Subsequently, following this pilot study, an article in late 2013 about the value of PRMR's in obesity also appeared on www.AskDrS.org.

Worldwide, researchers have continued to share their experiences at major conferences dedicated to specific wellness issues which impact obesity. For example, at the 2016 American Diabetes Association meeting in Boston, clinical results from a novel multi-modal approach (the TeLiPro concept) was presented by the West German Center for Diabetes and Health (Dusseldorf) and the German Institute for Telemedicine and Health Promotion (Efficacy of the Telemedical Lifestyle Intervention Program TeLiPro in Advanced States of Type 2 Diabetes-a Randomized Controlled Trial, Diabetes 65. Suppl. 1).

In this unique 12 week study under doctor supervision patients were engaged through five different modalities:

1. Telemonitoring
2. Telemedical Coaching (engagement)
3. Structured Lifestyle Intervention Program using the PRMR Almased®
4. Self-monitoring of Blood Glucose
5. Evaluated mental motivations training success

Additional recent successes and planned clinical trials regarding the use of PRMR's were discussed at the recent 5th Canadian Obesity Summit held in Banff Springs, Alberta Canada during late April Of 2017 (www.con-obesitysummit.ca). For those in attendance at the extensive program, sponsored by several organizations committed to reducing this obesity surge, each attendee learned from the prestigious Summit faculty of studies in healthy individuals designed to evaluate (versus standard diet) many different metabolic changes which impact areas of obesity and weight loss. These included improved sugar control, re-establishment of gut microbiome balance, alteration of energy metabolism, improved lipid oxidation and how various metabolic blood markers (ie, glucose, insulin, grehlin and leptin) can impact and support individuals who are obesity-challenged. Of particular interest were presentations by representatives from the University of Alberta Department of Agriculture, Food and Nutritional Science www.ualberta.ca.

In late May (24th - 27th) of 2017, the German Diabetes Association (DDG) held its annual scientific meeting in Hamburg, Germany (www.diabeteskongress.de) with four primary focus areas including individualized therapies for the obese/diabetes-challenged and how care research supports clinical research. The German Institute for Telemedicine and Health Promotion (www.ditg.de) exhibit offered attendees numerous summaries of clinical studies which had evaluated the utility of telemedicine and lifestyle interventions using PRMR where diabetes was involved.

Simultaneous with this scientific meeting in Hamburg a complete protocol and results tabulation from a diabetes randomized controlled trial was published online May 12, 2017, ahead of formal printing in *Diabetes Care*, the official publication of the American Diabetes Association (<https://doi.org/10.2337/dc17-0303>).

During the first week of the study, the TeLiPro group replaced breakfast, lunch and dinner with 1 gram of PRMR/kg normal body weight per meal (dissolved in 250 ml of water) and consumed 45 gram oil rich in n-3 fatty acids and 750 ml of vegetable juice each day. No additional snacks were permitted. During weeks 2 - 4, breakfast and dinner were replaced by PRMR and a low-carbohydrate protein-rich lunch was allowed. This lunch typically included 150 - 200 gram of fish or meal, 500 gram vegetables and not more than 50 gram carbohydrates from whole grain break or brown rice. During weeks 5 - 12, only dinner was replaced with PRMR. A total of 202 patients (102 in the TeLiPro group and 100 in the control group without the TeLiPro regimen) were involved with the study. 91% of the participants in the TeLiPro group completed the 12 week intervention with follow-up evaluation at weeks 26 and 52.

In summary, the results from these recent telemedical and telemedical coaching lifestyle structured intervention programs using Almased® were impressive:

- Significant reductions in A1C and even greater reduced weight, blood pressure and cardiovascular risk factors were demonstrated in the TeLiPro group when compared with the control group where no significant parameter changes occurred.
- The fast drop in blood glucose values was contributed to the dietary intervention of the PRMR
- The TeLiPro group reported a significant improvement in quality of life and beneficial change in eating behavior
- The TeLiPro group showed a significant decrease in the demand for diabetes medication (including insulin)
- Treatment superiority as compared to drug treatment and bariatric surgery using the TeLiPro multi-modal concept was demonstrated.

Today and most importantly, alternative therapies and intervention strategies for weight loss in diabetes challenged individuals are now evolving....and exist.

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