Combination Therapy – Continuous Glucose Monitoring (CGM) Technology with Digital Fitness as a Therapy for Type 2 Diabetes

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The Problem

Currently no technologies exist to analyze trends in data from CGMs to provide therapeutic exercise for type 2 diabetes

- Despite exercise being recognized as first-line therapy for type 2 diabetes
- Despite CGM technology being superior to fingerstick testing
- Despite non-insulin dependent type 2 diabetes representing 83% (25 million) of all patients with diabetes
- Despite high interest among non-insulin dependent patients with type 2 diabetes in using CGM combined with their fitness therapy
The Solution:
The right exercise at the right time for the right patient

Exercise = essential component of all treatment plans, can mitigate and reverse type 2 diabetes

However, patients have difficulty predicting whether exercise will stabilize or destabilize their blood glucose and related symptoms

What patients have now
• Fingerstick meters and exercise programs that are not diabetes specific and do not factor in blood glucose levels and other related diabetes metrics

NEED
• An automated digital tool to recommend the right exercise for the individual user based on their unique blood glucose profile captured by CGM

CONSUMERS:
Combination Therapy

Opportunity exists to combine CGM and DFTx into a powerful intervention for the global Type 2 diabetes market
Preliminary Studies

Study 1: Motivational enhancement therapy for exercise supported by CGM
Tested in stage 1 clinical trial for patients with insulin-dependent type 1 diabetes

Study 2: CGM with digital fitness as a therapy for type 2 diabetes
Proposed in visually-guided interviews of patients with non-insulin dependent type 2 diabetes and their healthcare providers

*90% patients reported interest in receiving a CGM, many frustrated not currently covered

*80%-90% healthcare providers expressed positive views of benefit for patients

Summary: CGM use has the potential to improve engagement with exercise and there is high interest among patients and healthcare professionals about using it to facilitate exercise in earlier stages of diabetes. Automated tools needed for scalability and sustainability.
AI powered mobile application to personalize exercise according to CGM data

Track CGM and exercise data over time to predict CGM & symptoms with exercise

Predictor variables
- Previous hour of CGM
- Current symptoms
- Exercise characteristics (difficulty, duration, muscle groups)
- Medication (type, timing, dose)
- Last meal (macronutrient composition)
Use of Blavatnik Funds

Stage 1 - Blavatnik Pilot ($100k)
*Develop software for CGM & digital fitness combination therapy
*Stage 1 trial: 1-month feasibility/acceptability trial with weekly user satisfaction interviews and ongoing software refinements
*Quality Improvement not research (distributed to patients with type 2 diabetes enrolled in GlucoseZone program through Yale-New Haven Hospital Livingwell Cares). Creates more naturalistic conditions, less red tape.

Staff ($90k): Software developer-$30k; Research assistant-$50k; Principal Investigator-$10k

Devices ($10k): CGM devices-$10k

Stage 2 – Blavatnik Development ($300k)
*Stage 2 trial: pure efficacy trial
*Intervention: combination therapy; Control: usual care
*Design: single-group nonrandomized crossover. Maximizes datapoints with exercise to feed machine-learning model, increases statistical power using within-participant comparisons.
*Outcomes: Weekly exercise minutes (target 150), HbA1c, blood pressure, quality of life
The Team

Garrett Ash, PhD (exercise physiologist, digital health interventionist)
   Yale Associate Research Scientist, CDA-funded

Stuart Weinzimer, MD (endocrinologist)
   Yale Professor, R-series funded
   World consensus panelist in continuous glucose monitoring
   Consultant and investigator for Medtronic and others

Mark Gerstein, PhD and Rajat Doshi (data scientists)
   Yale professor, R- and U-series funded, h-index = 180

Lisa Fucito, PhD (behavioral psychologist, digital health interventionist)
   Yale Associate Professor, R-series funded

Charles O’Connell (founder & CEO of Fitscript LLC) and team
   Software company providing digital exercise support to 18,000 users with diabetes
   Partnership with American Diabetes Association
   Professional relationship with CGM companies (Dexcom, Abbott, etc)
   Experience selling such product to individuals, healthcare systems, employers