Elements Required When Writing a Protocol
(An Explanation is Required if all Bullet are not Addressed)

Social and Scientific Value
A description of the scientific background, rationale and relevance. This should be referenced whenever feasible.

Public Dissemination of Trial Results
Describe any plans for public dissemination of results

Objective of the Study
Describe specific objectives and hypotheses

Outcomes
Clearly define primary and secondary outcome measures and when applicable, methods used to enhance the quality of measurements

Sample Size
Describe how sample size was determined

Randomization – Sequence Generation
Methods used to generate the random sequence, including details of any restrictions

Randomization – Allocation Concealment
Method used to implement the random sequence, clarifying whether the sequence was concealed until interventions were assigned

Randomization Implementation
Who generated the sequence, who enrolled participants and who assigned participants to their groups

Blinding
Whether or not participants, those administering the intervention, and those assessing the outcomes were blinded to group assignment. When relevant, how the success of blinding will be evaluated.

Statistical Methods
Statistical methods used to compare groups for primary and secondary outcomes

Fair Subject Selection – Recruitment of Participants
Description of the populations from which participants will be recruited, including details concerning location, age groups, gender, ethnicity and whether participants will be recruited from vulnerable groups

Favorable Risk-Benefit Ratio – Interventions Offering the Prospect of Health Related Benefit
Ordered enumeration and definition of research interventions offering the prospect of direct health-related benefits

Interventions Performed Solely to Answer the Research Questions
Ordered enumeration and justification of interventions performed solely to answer the research questions and generate generalizable knowledge

Clinical Balance
Description and justification of control and experimental arms, including modes and dosages of drug administration

Respect for Potential and Enrolled Subjects – Trial Monitoring Plan
Description and justification of a formal trial monitoring (safety and efficacy plan) including stopping guidelines for the trial, and how they were chosen

Communication of Protocol Changes and Trial Monitoring
Details concerning the method and timing of transmission of protocol changes and trial monitoring results to ViaHealth Clinical Investigation Committee