Appendix C. Data Management Plan

Quality Assurance and Control

Quality assurance and quality control is of utmost importance in a randomized clinical trial. Standardized protocols for all measurements were developed, and adherence to the written protocols was of paramount importance. All data collection personnel were certified as competent to make the required measurements by trained experts. The following provides an outline of the quality assurance and control program developed for PROPEL:

- Training and certification of all data collection personnel by experts
- Development of detailed manual of operations
- Retraining and recertification of all data collection personnel yearly
- Maintenance of logs of certified personnel
- Routine calibration of all equipment following manufacturers guidelines
- Maintenance of logs of calibrated equipment
- Performance of routine clinic site-visits and source document verification
- Setting realistic limits on data entry fields in REDCap
- Remote monitoring of data entry, missing data and lag times through REDCap
- Creating both real-time and subsequent executable data quality checks in REDCap
- Querying appropriate personnel regarding missing data
- Preparing quality control reports for personnel, investigators and Data and Safety Monitoring Board

There were logistical issues that limited the research management staff's ability to perform site visits and monitor data collection readily at 18 remote clinics (budgetary restrictions, time constraints, limited staff, etc.). Therefore, consent was obtained from patients who were willing to have their intervention sessions audio and video recorded; consent status was data entered and tracked in REDCap. These recordings were used as a means of monitoring to ensure treatment fidelity. Participants who signed the consent to record their sessions were informed before each visit begins when the visit is bring recorded.

Data Management

Assessment Data - REDCap

All data collected by the assessment team at SV, BV, and at month 6, 12, 18 and 24 assessment visits was transferred from paper form to the Research Electronic Data Capture (REDCap) system[5] through data entry by study personnel. REDCap is a secure, HIPAA-compliant, web-based application that can be utilized for electronic collection and management of research and clinical trial data. Study data and electronic data capture tools are housed in a secure data center at Pennington Biomedical, and all web-based information transmission is encrypted. The server is backed up nightly and is protected by an enterprise network security firewall. REDCap was accessed through the Pennington Biomedical secure website, https://redcap.pbrc.edu, where research personnel were required to enter user ids and passwords previously approved and set up by the Pennington Biomedical REDCap Administrator.

The level of user access and privilege was determined on an individual basis and relied upon each user's role in the study and clinics they were associated with. Only select project management personnel were able to edit participant record IDs or export data; the data collection staff were only able to view, enter, and edit (not export) the participant data and run quality checks for the clinics with which they were associated. All data entered were run through multiple checks for internal consistency and biologic plausibility; these were conducted in REDCap with either real-time error messages and data stoppage rules or user-initiated query reports, as well as with study-specific SAS programs designed by the data manager. Missing or questionable data were assessed and corrected by research staff at the clinics or project management staff at Pennington Biomedical. All users were thoroughly trained in the use of the PROPEL REDCap data entry and validation system. Once it was determined that data collection, entry and verification was complete, the REDCap project was locked so that users were no longer be able to edit the data, but investigators were still able export and preserve the data. The trial data dictionary and associated metadata were developed by the data manager using the REDCap data dictionary functions.

Intervention Data – Computer Tracking System (CTS)

The internet-based Computer Tracking System (CTS) facilitated intervention delivery, treatment fidelity, scheduling of intervention visits with patients, and tracking of process measures for intervention delivery, such as attendance. The CTS allowed for tailoring the intervention to individual patients, and it was used by the intervention team to quantify process measures related to intervention delivery. Specifically, it was used to review participant session attendance, receipt of session materials, adherence to the diet based on the weight graph, and weight loss. These process data were provided in reports generated by the CTS, and these data were available at the study, clinic, counselor, and patient level. The CTS was housed on a HIPAA compliant server.

Assessment and Intervention Data Confidentiality

The assessment team, health coach, and project and data management staff had access to personally identifiable private information about human subjects. All volunteers were assured of their confidentiality both verbally and in the informed consent form. The facilities were strictly limited to the study staff, clinics and research volunteers. All study records were locked in a secure area in a locked filing cabinet. Access to these areas was limited to the clinical and research support staff and the study investigators. Study records were filed according to study identification numbers rather than by name. All forms in the chart, with the exception of the consent form and participant contact form, displayed only the ID number. Electronic data storage was similarly restricted in a password-protected, encrypted website.

Data Sharing

De-identified data and supporting documents will be made available upon request to the Principal Investigator: peter.katzmarzyk@pbrc.edu. Data availability will begin one year after publication of the primary outcomes paper.[6] Data will be available to researchers whose proposed use of the data has been approved by the PROPEL Publications Committee for scientific publications. Data will be transferred with a signed data use agreement with the Pennington Biomedical Research Center.