

CLINIC VISIT PROCEDURES IN A PROSPECTIVE STUDY OF ENVIRONMENTAL AND GENETIC FACTORS AND PUBERTY: THE CYGNET STUDY

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Background: The CYGNET Study (Cohort study of Young Girls' Nutrition, Environment, and Transitions) is a prospective study examining predictors of early puberty in young girls. Part of the Bay Area Breast Cancer and the Environment Research Center, it is one of three cooperative studies nationwide enrolling 6-8 y old girls who are being followed longitudinally. CYGNET Study participants are members of Kaiser Permanente Northern California in the San Francisco Bay Area. Clinic visits are held at Kaiser facilities in Oakland, San Francisco, and San Rafael.

Methods: Study Description and Consent/Assent. A CYGNET Study participant's yearly clinic experience begins the moment she and a parent or legal guardian (usually the biological mother) walk through the clinic door. They are welcomed in English or Spanish, provided refreshments and meet the clinic staff. A research assistant sits down with the child and parent, explains the study and clinic procedures, and obtains informed consent from the parent and assent from the child. Both child and parent are encouraged to ask questions at this time and throughout the clinic visit. After obtaining signed consent and assent, the phlebotomist gives a blood draw demonstration and answers any questions related to biospecimen collection.

Data collection from Parent/Guardian. The research assistant who performed the consent/ assent process usually administers a standardized, structured interview to the parent in a private room. Self-administered questionnaires are given to the parent; these may be filled out in the clinic in a private setting or in the waiting room, which also functions as a play area for the children. Self-administered questionnaires include standardized psychosocial instruments (Behavior Assessment System for Children, 2nd Edition (BASC-2) Parental Rating Scale; the Family Environment Scale (FES); and the Center for Epidemiologic Studies Depression Scale (CES-D)), residential history, and contact information.

Data collection from Child. Prior to anthropometry, the parent answers screening questions about the child, verifying her fitness for bioelectrical impedance analysis. Anthropometry is usually conducted concurrent with the parent interview. The child changes into a paper gown before measurements begin. Height is measured using a fixed stadiometer, and weight is measured on standardized scales. Bioelectrical impedance analysis is conducted using a Tanita Scale and an RJL bioelectrical impedance analyzer. After anthropometry, the parent is notified and more detailed description of Tanner staging procedures is given. Tanner stage is assessed visually, and palpation is conducted if necessary to assess breast development. After completion of Tanner Staging, the girl and her parent are left in privacy to change back into her clothes. The next data collection activity is biospecimen collection. The phlebotomist draws a blood sample if the child is willing, and obtains a urine sample. All biospecimen supplies are provided by the Centers for Disease Control and Prevention. At a convenient time, the girl is also instructed in how to use a pedometer.

Post Clinic Data Collection. If there is limited time, the parent is given the option of taking home the self-administered questionnaires to be mailed back as her convenience. The parent and child are instructed on how to keep a one-week log of the pedometer's recordings. Instructions and directions for participating in periodic 24-hour dietary recall interviews, administered by Cincinnati investigators, are also provided.

In Clinic Compensation. After anthropometry and blood draw, the child is provided the opportunity to draw an item from a grab bag, and is also given a choice of books. The waiting room is equipped with activities to occupy the girl while her parent is interviewed, including activities that may result in another gift for the child, such as construction of a beaded jump rope or bracelet. After completion of all activities, a nominal gift certificate, canvas bags, stainless steel mugs, or other items are provided to thank the participants.

Conclusion: Clinic activities in the CYGNET Study revolve around collecting high-quality data in a safe, supportive and fun atmosphere for the girls and their parents/guardians. The initial experiences are informing continuing procedures for Year 2 and subsequent clinic visits and activities in the CYGNET Study.