**Title**: Use of Wearable Devices in PWS Clinical Trials: Formative Data to Inform a Feasibility Pilot

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**Introduction**: Directly measured, objective outcomes are needed for Prader-Willi syndrome (PWS) clinical trials. Heart rate variability (HRV) has been associated in non-PWS studies with appetite/food exposure, adolescent food cravings and food signals, diseases such as diabetes, and psychiatric disorders such as binge eating disorder (Yoshioka & Terasaki, 1994; Friederich et al., 2006; Green et al., 2009; Udo et al., 2014; Wu et al., 2020). Alterations in HRV have been reported in small PWS studies that did not use consumer wearable devices (e.g., smartwatches) to collect data (Purtell et al., 2013; Wade et al., 2000). Technological improvements in wearables may make them suitable for collecting HRV and other data in PWS studies. Our aim was to assess the feasibility of using wearable devices in PWS studies and formats for collecting daily contextual data from caregivers.

**Method**: We conducted two focus groups of English-speaking participants: one with parents of a child with PWS aged 7-17 years (n=9), and one with adults living with PWS (n=7). Focus groups were moderated using a semi-structured guide tailored to each group (e.g., reading level). A quasi-deductive analysis was conducted on transcripts to elicit themes.

**Results**: Parents mostly identified as mothers (78%), were comfortable with technology (100%), and had participated in a PWS clinical trial (78%). Adults with PWS had a median age of 21 years (IQR= 18-28), were mostly female (57%), white (71%), were comfortable with technology (86%), and had participated in a PWS clinical trial (57%). Participants of both focus groups endorsed the feasibility and acceptability of a smartwatch versus a stick-on patch for collecting HRV and other data. Over half of the adults with PWS volunteered that they wear a smartwatch. Those who do not wear it at night agreed that they could. Similarly, most parents reported that a smartwatch would be unintrusive and even desirable for their child with PWS, whereas there were concerns from some about sensory issues, compulsive removal, and lack of engagement (i.e., no screen) with the patch. For daily collection of contextual data, participants from both focus groups preferred flexibility (e.g., email or text). Parents suggested that use of wearables may be less successful in younger children with PWS and those who are more cognitively impaired.

**Discussion:** A smartwatch was endorsed as acceptable and feasible for collecting HRV data. However, age and functioning level of individuals with PWS should be considered, and contextual data collection options need to be developed and piloted. Future plans include a focus group of Spanish-speaking parents to validate or add context to the findings from English-speaking groups and a pilot study using smartwatches to measure HRV in adults with PWS in a group home setting.

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