

Effects of Tobacco Heating System (THS) Use on Weight Gain

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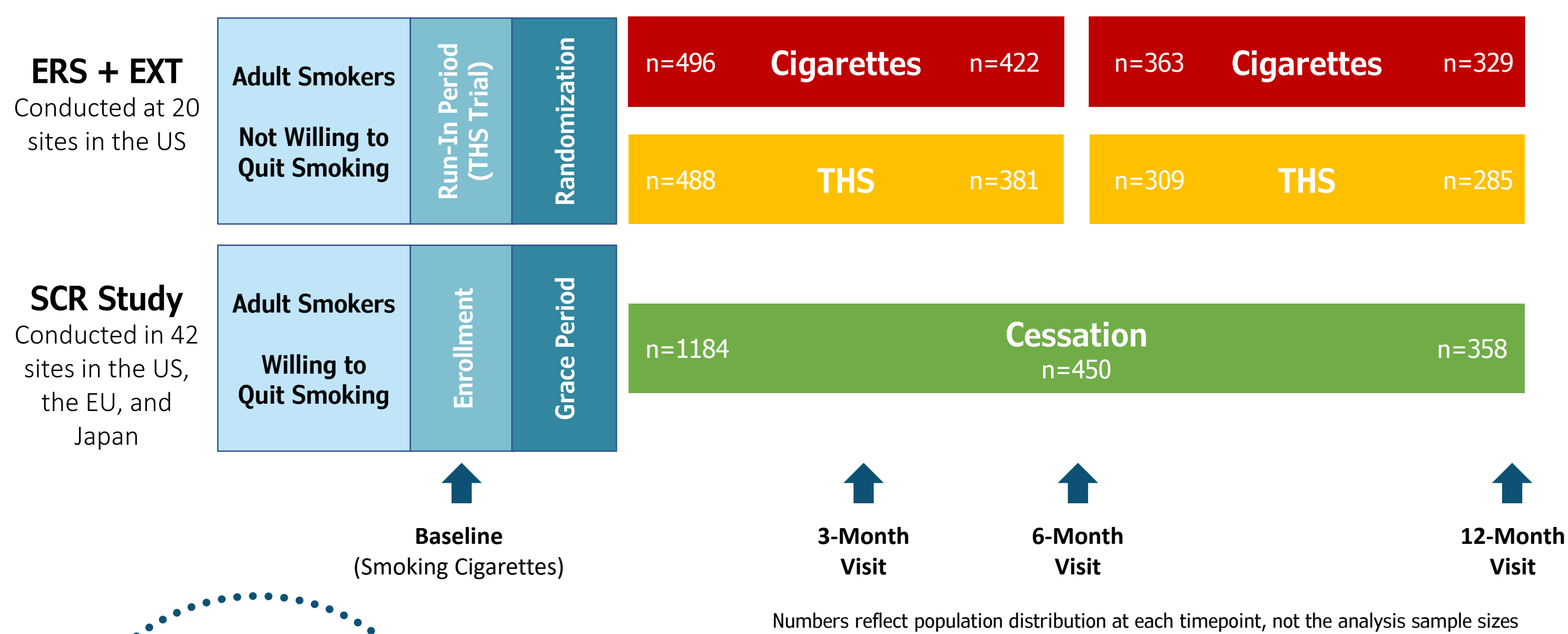
Background

- Smoking cessation is the best choice for smokers who want to reduce their risk of developing smoking-related diseases and increase their life expectancy.
- However, long-term quitting rates are still very low. In US, <10% of smokers successfully quit smoking every year [1]. Then, further, 80% of smokers who are able to successfully quit smoking for 1 year report a 4- to 5-kg weight gain, which has been suggested to be a factor that can compromise smokers' motivations to quit smoking [2].
- Philip Morris International (PMI) has developed and assessed a heated tobacco product (HTP), the Tobacco Heating System (THS), which is currently sold in over 50 markets around the world under the brand name IQOS®. This product heats the tobacco instead of burning it and, therefore, is a better alternative to cigarettes for smokers who would otherwise continue to smoke.
- The US Food and Drug Administration (FDA) has conducted a rigorous science-based review of PMI's THS product and deemed that the marketing of this product is appropriate for protection of public health and thus authorized it for sale in the US.

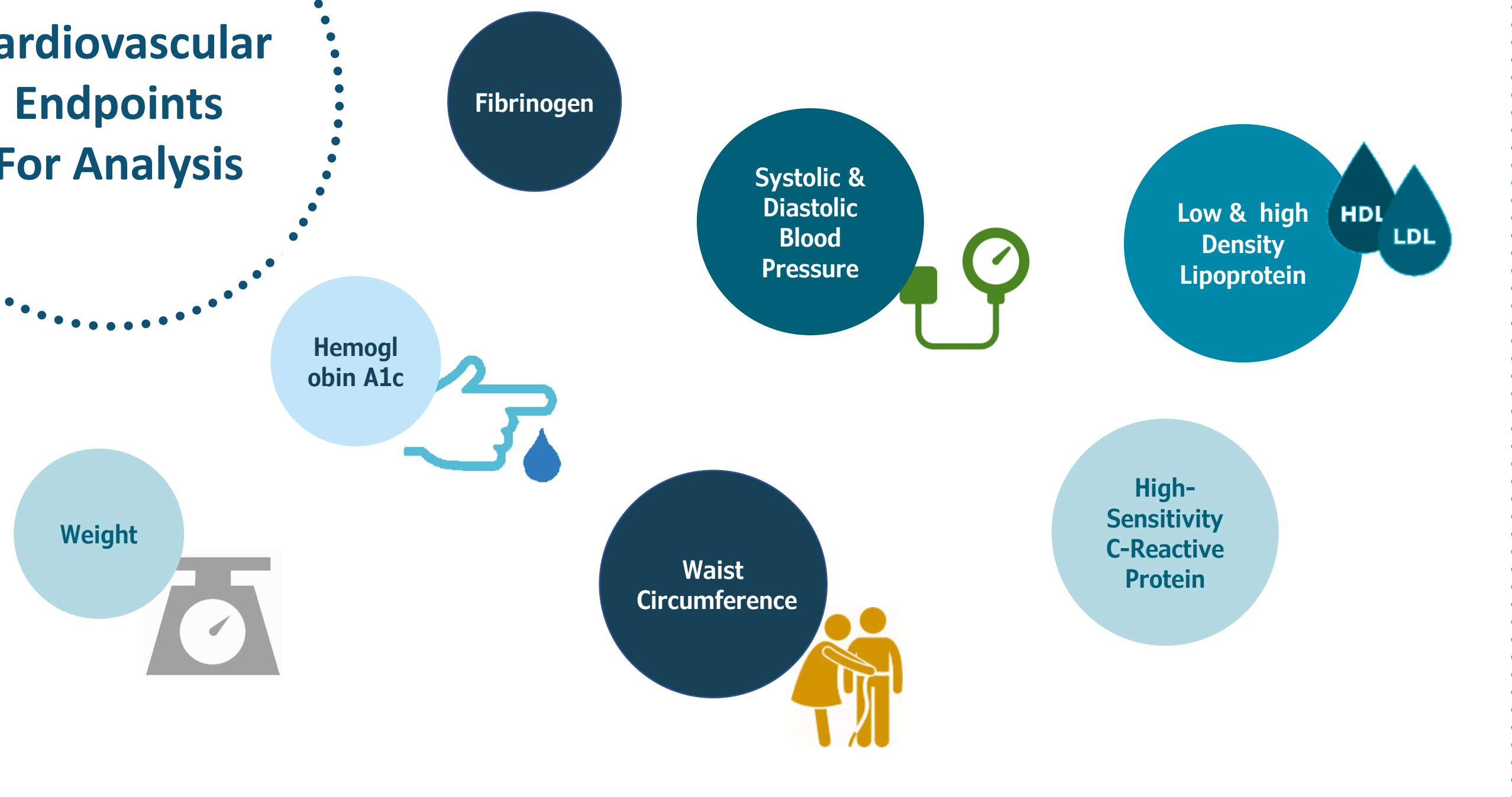
Hypothesis

Smokers who switch to THS improve their cardiovascular markers of risk relative to those who continue to smoke cigarettes. This includes lower weight gain after switching compared with that after smoking cessation.

Methods



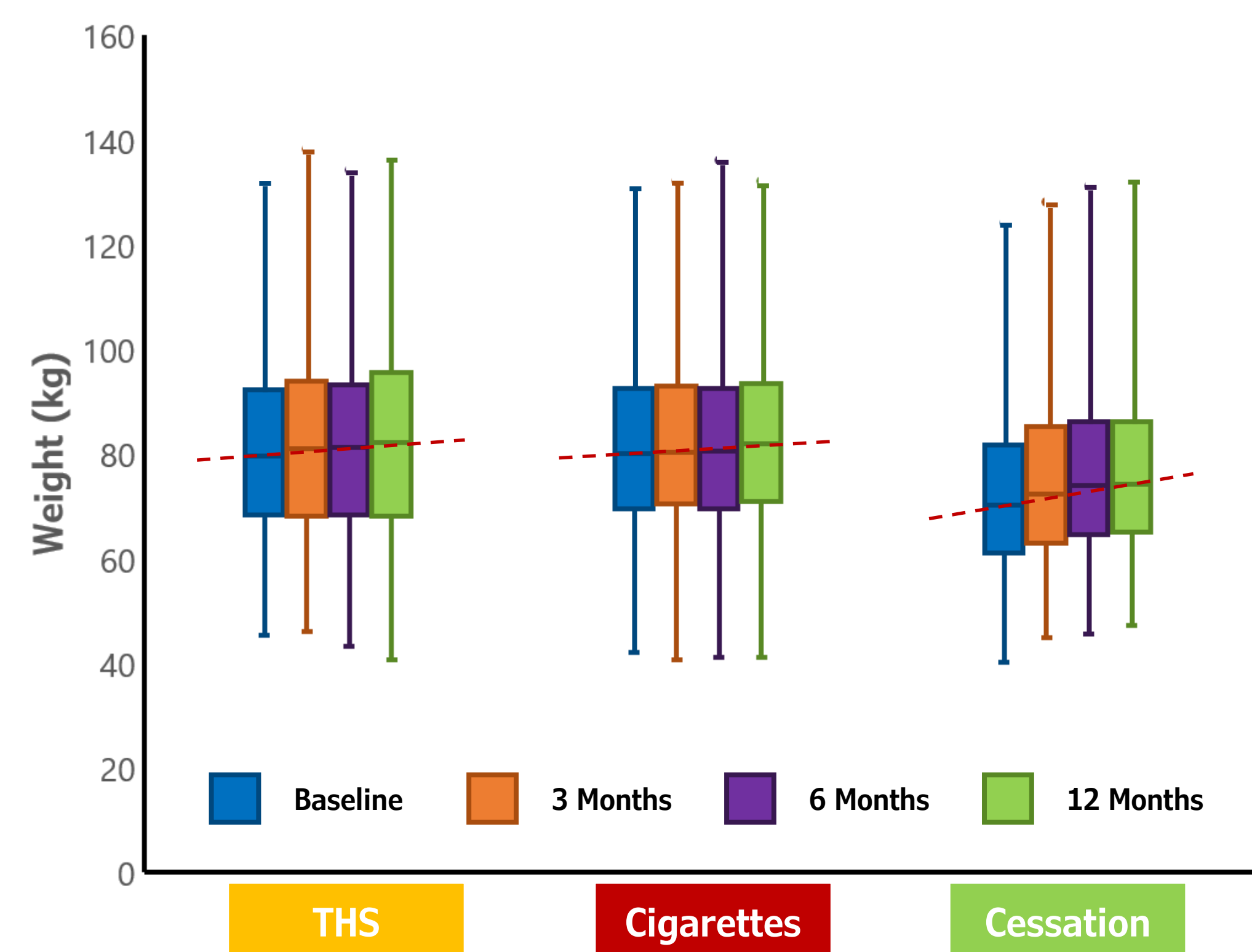
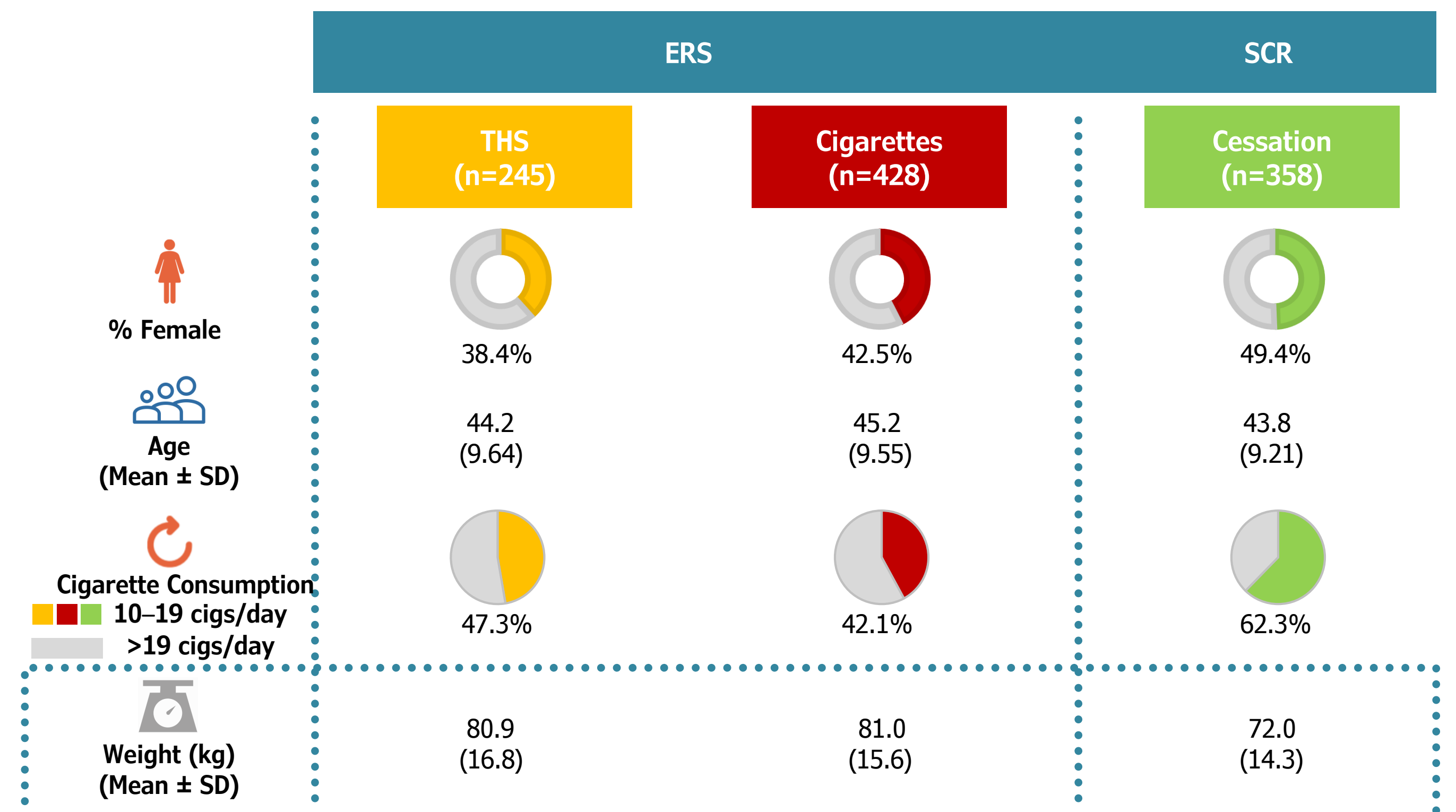
Cardiovascular Endpoints For Analysis



Analysis

These endpoints were analyzed by using a mixed effect model using the original values with visit, baseline values (and interaction between baseline values and visit), sex, race (Caucasian), age, product-use pattern (and interaction between product-use pattern and visit), and smoking intensity as fixed effect factors and site as a random effect. The results are presented as adjusted least squares (LS) means and confidence intervals (CI).

Population



Weight was fairly stable over the 12-month study period both in the THS and cigarette groups. But, there was an increase over the same period in the cessation group.

Cardiovascular Markers	THS - Cigarettes LS Mean (95% CI)	THS : Cigarettes (%) Geo LS Mean (95% CI)
Weight (kg)	0.693 (-0.173, 1.56)	
Waist Circumference (cm)	0.168 (-1.70, 2.03)	
Carboxyhemoglobin (%)		96.9 (93.9, 100)
s-Intercellular Molecule Adhesion1 (ng/mL)		68.3 (60.9, 76.7)
White Blood Cell Count (GI/L)	-0.413 (-0.694, -0.131)	
HDL-cholesterol (mg/dL)	1.75 (-0.160, 3.65)	
LDL-cholesterol (mg/dL)	1.15 (-3.21, 5.51)	
Systolic Blood Pressure (mmHg)	1.17 (-0.734, 3.08)	
Diastolic Blood Pressure (mmHg)	0.295 (-1.03, 1.62)	
HbA1c (%)	0.0249 (-0.0320, 0.0818)	
hs-CRP (mg/L)		90.0 (77.0, 105)
Fibrinogen (mg/dL)		99.2 (95.9, 103)

Conclusions

Because severe weight gain is known to increase the risk of cardiovascular diseases, the limited weight gain and absence of increase in cardiovascular risk factors observed upon switching to THS adds to the body of evidence suggesting potential of THS use to reduce the risk of smoking-related diseases relative to continued cigarette smoking [3].

References

- Center for disease control and prevention, Smoking Cessation: Fast Facts (May 2020). https://www.cdc.gov/tobacco/data_statistics/fact_sheets/cessation/smoking-cessation-fast-facts/index.html
- Germeroth et al, Addict Behav. 2018. Post-cessation weight gain concern as a barrier to smoking cessation: assessment considerations and future directions.
- Philip Morris Modified Risk Application accessed on 09.06.2020. <https://www.fda.gov/tobacco-products/advertising-and-promotion/philip-morris-products-sa-modified-risk-tobacco-product-mrtp-applications>