The scientific question
Is there an effect of the treatment on the proximal response? And is there an effect of the treatment if the individual is currently experiencing stress?

Stratified micro-randomized trial
- Participant data:
  \[ \{ O_0, O_1, I_1, A_1, \ldots, O_t, I_t, A_t, \ldots, O_T, I_T, A_T \} \]
- The proximal response, denoted by \( Y_{t, \Delta} \), is a known function of the participant’s data within a subset window of length \( \Delta \). For example,
  \[
  Y_{t, \Delta} = \Delta^{-1} \sum_{s=0}^{\Delta} 1 \{ X_{t+s} = \text{"Stressed"} \}
  \]
- We consider binary actions (i.e., \( A_t \in \{0, 1\} \)). The randomization probability \( \rho_t(H_t) := \text{pr}(A_t = 1 | H_t) \) is given by
  \[
  \frac{N(x) - \sum_{s=0}^{\Delta} |\lambda_s A_s + (1 - \lambda_s) \rho_s(H_s)| 1[X_s = x]}{1 + \sum_{s=0}^{T} 1[X_s = x] | H_t}
  \]

Markovian generative model for the smoking cessation study
- For each episode type (i.e., \( x \in \{0, 1\} \)), the probability that the next episode will be a stress episode: \( \tilde{W} = (6.7\%, 51.9\%) \)
- For each episode type (i.e., \( x \in \{0, 1\} \)), the average episode length: \( \tilde{Z} = (10.9, 12.0) \)
- Inputs are informed by summary statistics from a subset of data (Sarker et al. 2017) collected in an observational, no treatment, smoking cessation study of 61 cigarette smokers (Saleheen et al. 2015).

Table 1: \( P_{(0)} \), No-Treatment transition Matrix constructed from inputs \( (\tilde{W}, \tilde{Z}) \)

<table>
<thead>
<tr>
<th></th>
<th>Pre-peak</th>
<th>Peak</th>
<th>Post-peak</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-peak</td>
<td>0.90</td>
<td>0.00</td>
<td>0.10</td>
</tr>
<tr>
<td>Peak</td>
<td>0.00</td>
<td>1.00</td>
<td>0.00</td>
</tr>
<tr>
<td>Post-peak</td>
<td>0.19</td>
<td>0.00</td>
<td>0.80</td>
</tr>
</tbody>
</table>

Example evaluation of sample size calculator
- Markov model allowed us to use fewer summary statistics from the small noisy dataset.
- This may lead to bias, which is problematic if results in sample sizes for which the power to detect the desired effect is below the specified power.
- We thus use the small data set to guide our assessment of robustness of the sample size calculator.
- A complex semi-Markovian generative model is proposed through exploratory data analysis.
- Such complex alternatives may be due to noise and not reflect the behavior of trial participants.

Table 3: Logistic regression parameter estimates. Response is indicator of current episode being a stress episode.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Estimate</th>
<th>Std. Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intercept</td>
<td>-2.83</td>
<td>0.10</td>
</tr>
<tr>
<td>1L Stress Ep.</td>
<td>2.75</td>
<td>0.20</td>
</tr>
<tr>
<td>2L Stress Ep.</td>
<td>0.71</td>
<td>0.22</td>
</tr>
</tbody>
</table>

Table 4: Achieved power under semi-Markov model

| Achieved Power | 93.6 | 88.0 | 93.4 |

References