"A"-"Not A" Replicated Mixed Method Development

Daniel Ennis[1], Pallavi Mohekar,[*] Benoît Rousseau[1], Simeon Chow,[*] Jessica Zdinak[2]

[1]The Institute for Perception, USA; [2]Altria Client Services, USA

Objective

To develop an overall discrimination procedure with high power to investigate sensory differences between products requiring single sample evaluations

1. Background

- Due to the need for limited exposure, many consumer products are not well-suited to traditional discrimination methods such as the m-alternate forced choice (m-AFC), duo-trio, triangle, and tetrads

- Examples of products include pharmaceutical products, tobacco, e-vapor products, chewing gum, shaving products, and personal care such as body washes or shampoos

- Substantial Equivalence (SE) is one of the pathways to legally market and distribute new tobacco products

- Tobacco manufacturers often need to demonstrate that new products are substantially equivalent to an already authorized market product

2. Choice of Method and Design

- To meet the background objectives, a method is required that has high statistical power, no attribute specified, monadic presentation, and limited product exposure

- The "A"-"Not A" method is theoretically comparable in power to the 2-AFC[1] and requires consumers to be familiar with the items assessed through the use of an effective familiarization procedure

- Application of the method, on products such as moist smokeless tobacco (MST), requires investigation regarding the familiarization procedure

- It is necessary to develop an optimal at-home familiarization time period for consumers to become sufficiently familiar so that their responses to the "A"-"Not A" are stabilized
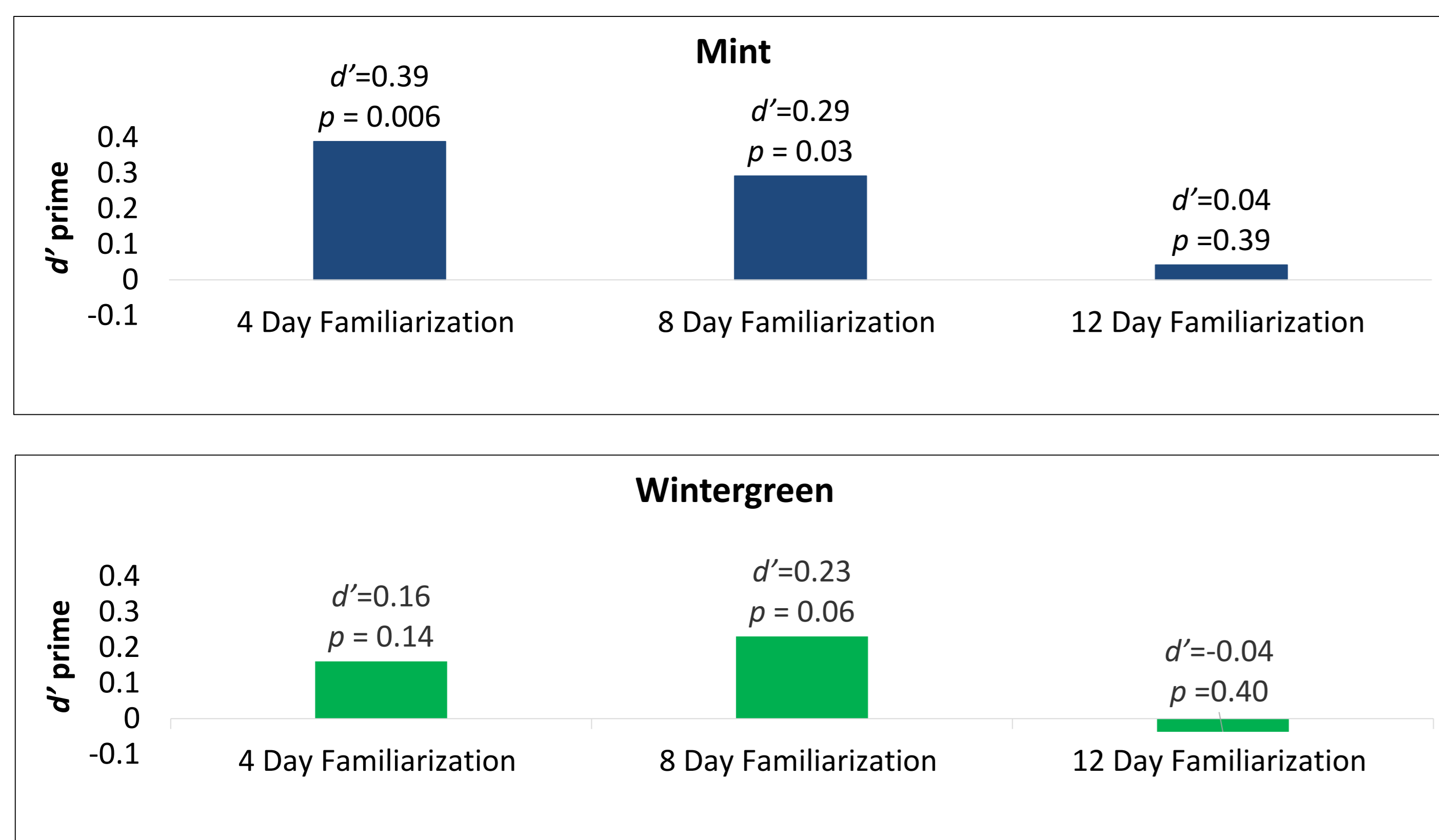
- Analysis for heterogeneity of consumers is conducted with the Dirichlet-multinomial model (DM)[2]

- The replicated mixed design provides random sequences of replicated items (shown in Figure 1) to improve power[3]

Figure 1: Illustration (with MST cans) of replicated mixed model "A"- "Not A" presentation orders. Color is for illustration, codes are used

Resp 1
Resp 2
Resp 3
Resp 4
Resp …

4. Results

- Analyses involved calculating d' values, a measure of sensory discrimination, combined over all subjects

- Figure 3 summarizes the CLT d' values after each familiarization period

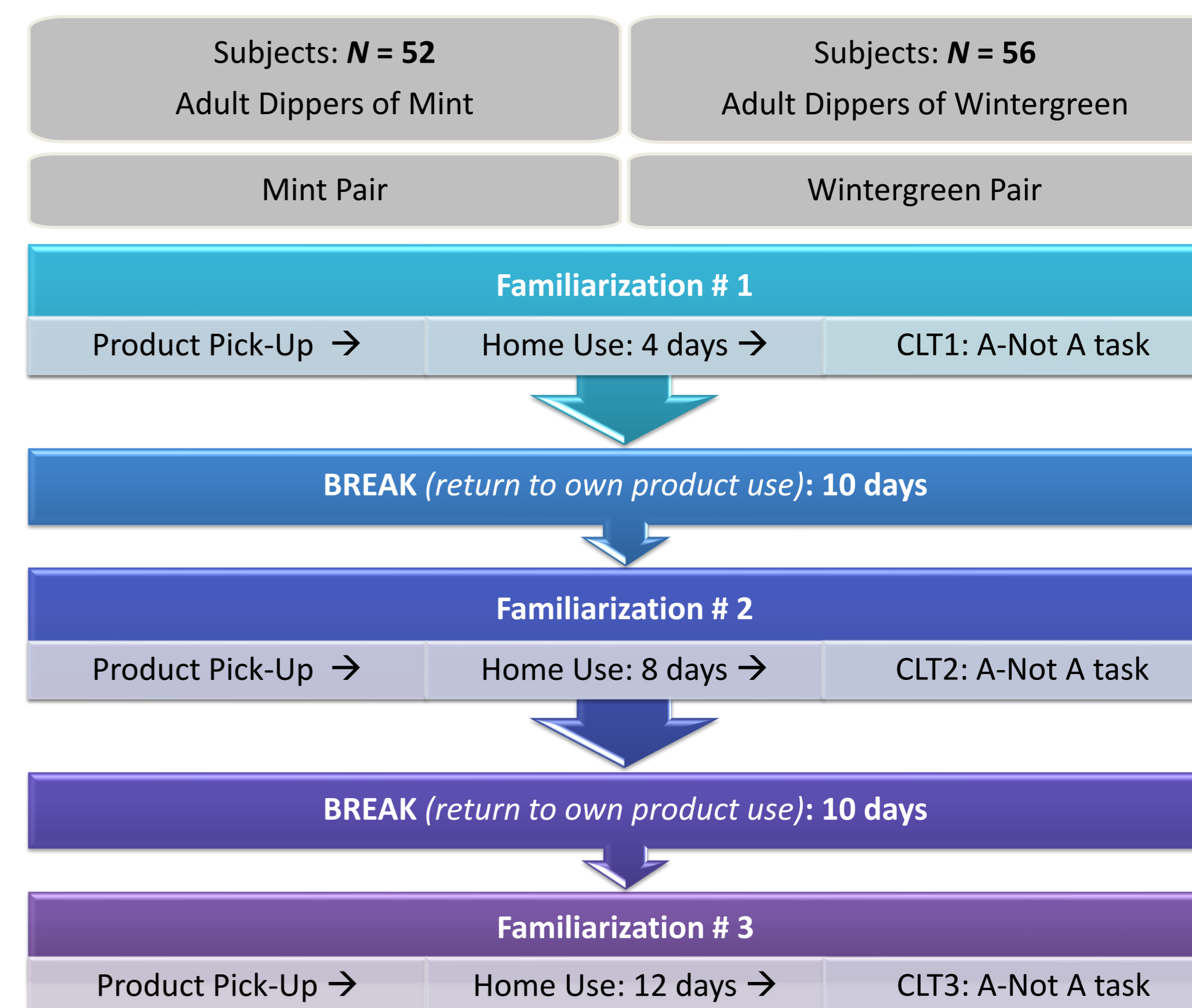- Performance did not decrease over the 5 samples tested within a session

Figure 3: "A"- "Not A" Discrimination by Session

Mint

d'=0.39
$p = 0.006$ d'=0.29
$p = 0.03$ d'=0.04
p =0.39

4 Day Familiarization   8 Day Familiarization   12 Day Familiarization

Wintergreen

d'=0.16
$p = 0.14$ d'=0.23
$p = 0.06$ d'=-0.04
p =0.40

4 Day Familiarization   8 Day Familiarization   12 Day Familiarization

3. Procedure

- Two different sets of Adult Dippers for the two flavors are used

- Product: Moist Smokeless Tobacco
    – For each flavor, the same product pair was used throughout the protocol

- Figure 2 illustrates the experimental protocol

Figure 2: Research flow

Subjects: N = 52
Adult Dippers of Mint

Subjects: N = 56
Adult Dippers of Wintergreen

Mint Pair

Wintergreen Pair

Familiarization # 1

Product Pick-Up →   Home Use: 4 days →   CLT1: A-Not A task

BREAK (return to own product use): 10 days

Familiarization # 2

Product Pick-Up →   Home Use: 8 days →   CLT2: A-Not A task

BREAK (return to own product use): 10 days

Familiarization # 3

Product Pick-Up →   Home Use: 12 days →   CLT3: A-Not A task

Home Use Familiarization

- In a pair, one of the products was labelled with a 3-digit blinding code "###" and the other with "Not ###"

Central Location Test (CLT)

- Each respondent evaluated five samples using a replicated mixed model "A"-"Not A" method (Figure 1)

- Each sample was portioned with a portion size of 5g

- Evaluated for five minutes each, with one-minute washout period between successive samples

- Questionnaire:
  ➢ Is the sample?
     ☐ ###   ☐ Not ###
  ➢ How sure are you of your selection?
     ☐ Sure   ☐ Not Sure

5. Conclusions

- The "A"-"Not A" methodology was evaluated to compare samples of moist smokeless tobacco following 4, 8, and 12-day familiarization periods

- A 12-day familiarization period led to a reduction in performance as measured by an index of sensitivity, d'

- A lack of demonstrable sensitivity at 4 days for the Wintergreen sample showed that the 8-day familiarization period was preferred

- The results showed that five samples can be tested in a single CLT session without loss of sensitivity

6. Applications and Limitations

- Due to product limitations, the "A"-"Not A" discrimination procedure developed here may be used in assessing potential difference between products where exposure in a session must be limited

- The method assumes the numerical label association of the alternative products during the evaluation stage. Some subjects, who recall the difference but not the association, may require a reminder set prior to evaluation in the CLT portion thus reducing the opportunity to replicate

- Although a 10-day rest period occurred between the temporal sets, separate groups for each set may perform differently and, in particular, not show the performance decrement evident in the 12-day set

References

1. Bi, J. and Ennis, D. M. (2001). The power of the "A"-"Not A" method. *Journal of Sensory Studies,* **16(4)**, 343-359.
2. Ennis, D. M. and Bi, J. (1999). The Dirichlet-multinomial model: Accounting for inter-trial variations in replicated ratings. *Journal of Sensory Studies,* **14(3)**, 321-345.
3. Bi, J. and Ennis, D. M. (2001). Statistical models for the A-Not A method. *Journal of Sensory Studies,* **16(2)**, 215-237.

*Former employees of Altria Client Services