

# Methods for revising a mindfulness trial to a remote platform during COVID-19

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## Purpose

- To describe the necessary adaptations made to an experimental trial examining mindfulness training on stress and smoking behavior. The study was halted in February 2020 due to COVID-19 social isolation requirements. Investigators revised the trial to include remote recruitment, enrollment and data collection methods.

## Background

- Mindfulness training (MT) is an attention regulation and stress-reduction program that can be used in user remote settings.<sup>1</sup>
- Previous studies show that smokers in a MT intervention (in person, twice weekly for a month) show a decoupling of nicotine craving and smoking behavior (baseline  $r=0.58$ , post-treatment  $r=0.13$ ).<sup>2</sup>
- MT practice leads to reductions in cigarette use and correlates with reductions in stress reactivity regions of the brain.<sup>2,3</sup>
- Previous studies show oxytocin (OT) can attenuate nicotine withdrawal, decrease craving, and self-administration of multiple drug types.<sup>4</sup>
- MT and oxytocin have treatment effects that represent similar neural pathways relating to stress, anxiety, and social cue interpretation that may work in tandem to support smoking restraint after a stressor.

## Methods

### Original In-person study

#### Design

- Randomized Control Trial, 2 x 2 full factorial design
- N=240 current Los Angeles smokers reporting at least 10 cigarettes per day and registering a carbon-monoxide level of at least 10ppm.

#### Treatments

- MT: Two 10-min Headspace audio recordings daily for 14 days
- Control: Two 10-min TedTalk audio recordings daily for 14 days
- OT: 40IU Pitocin (10IU/1mL) delivered intranasally by 2 mL atomizers over 15-min.
- Control: Saline (0.9%, 4mL) delivered intranasally by 2 mL atomizers over 15-min

#### Measures

- Behavior: Smoking delay time, smoking urge, cigarettes smoked
- Physiology: Salivary cortisol, heart rate variability

### Remote study

#### Design

- Randomized Control Trial, parallel group design, MT vs. control
- N=240 California smokers reporting at least 5 cigarettes per day, and an interest in quitting smoking

#### Treatments

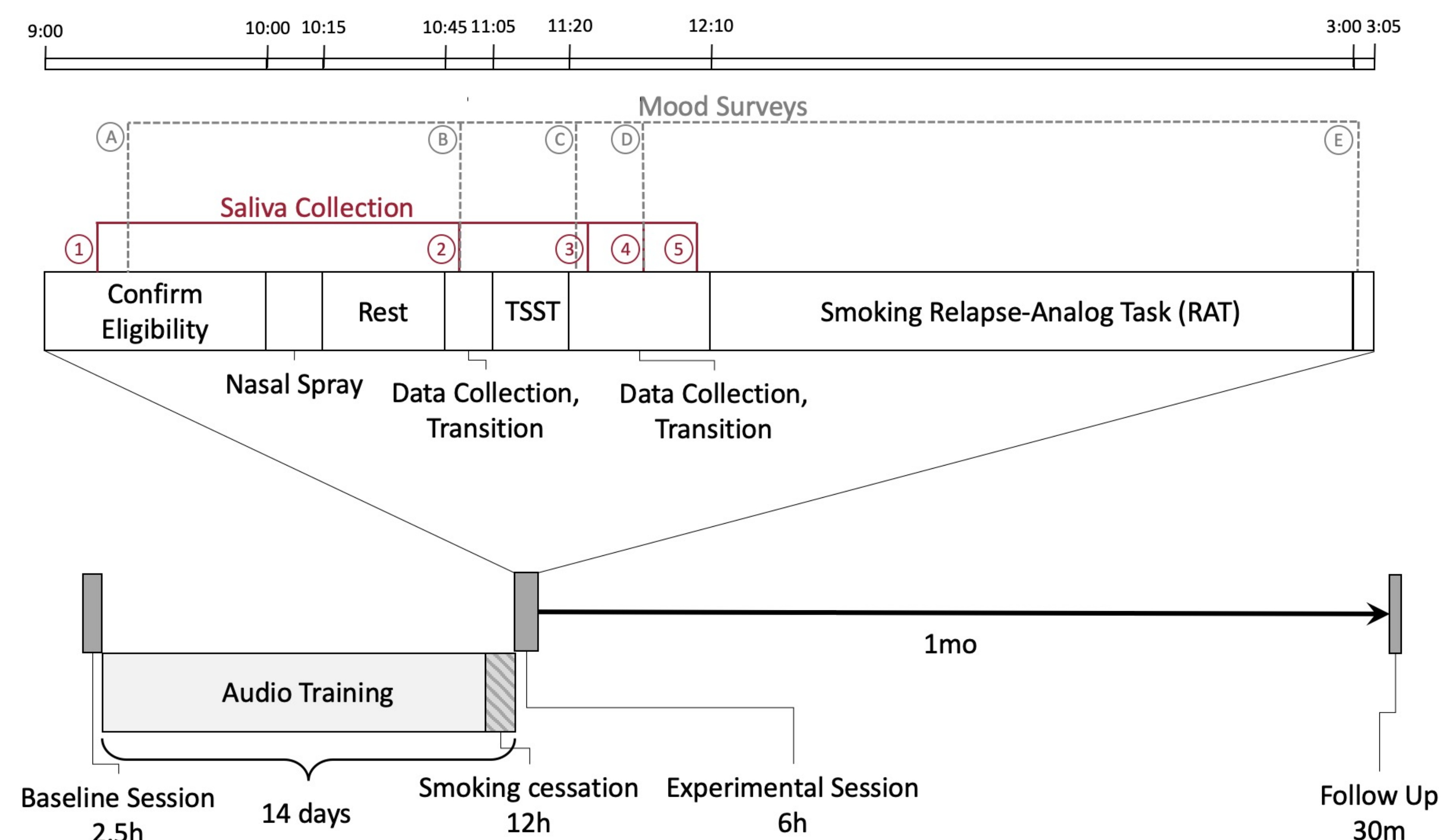
- MT: Two 10-min Headspace audio recordings daily for 14 days
- Control: Two 10-min TedTalk audio recordings daily for 14 days

#### Measures

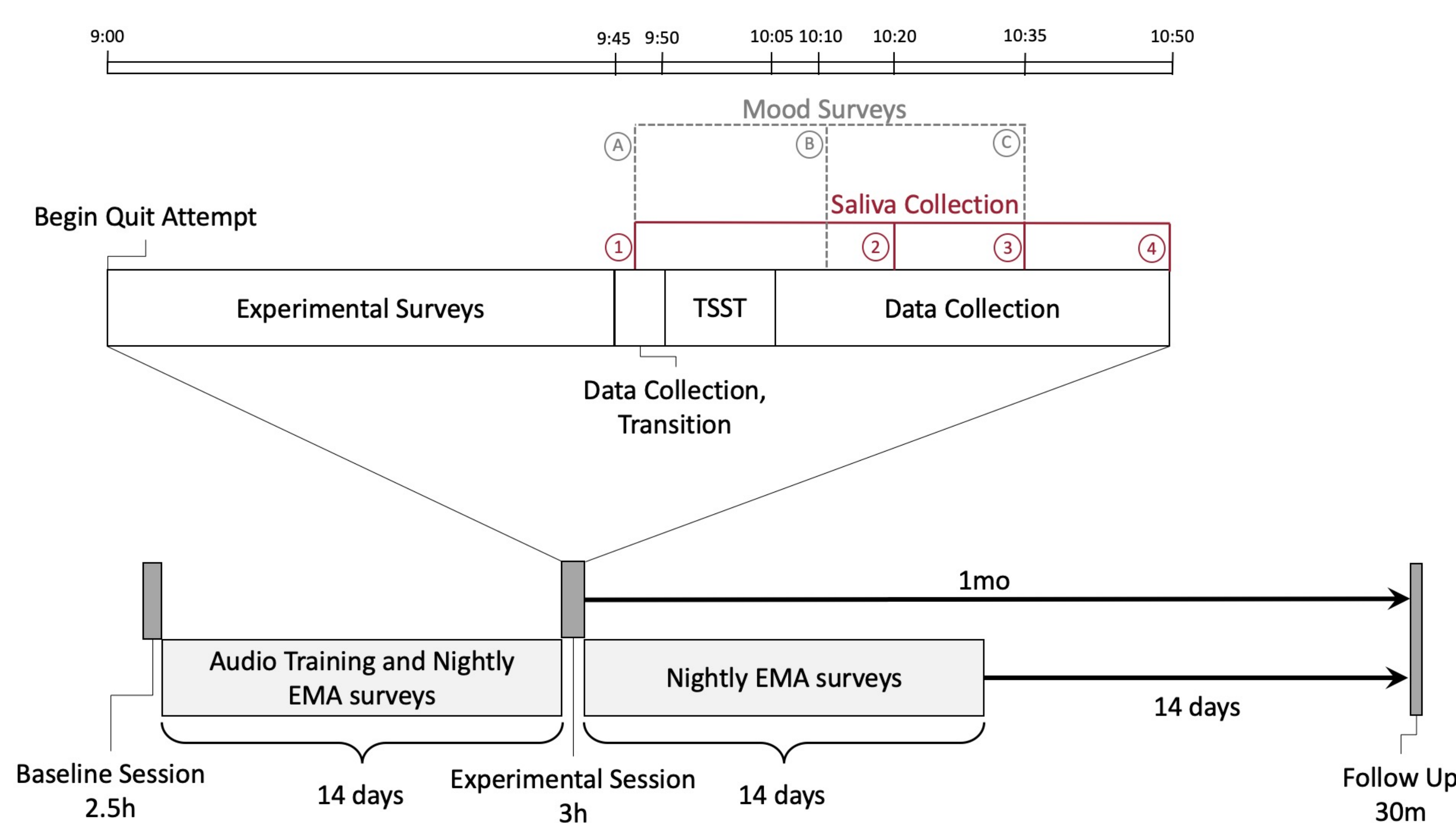
- Behavior: Daily mindful practice, daily smoking, smoking lapse
- Physiology: Salivary cortisol, salivary oxytocin

## Results

**Figure 1. Original in-person study design and measures**



**Figure 2. Adapted remote study design and measures**



## Discussion

- Due to COVID-19 restrictions, the adapted study includes remote versions of eligibility interviews and data collection, including online computerized tasks, and ecological momentary assessment.
- Zoom technology is utilized to conduct participant interviews, deliver a remote Trier Social Stress Task, and demonstrate proper saliva collection protocol.
- Four weeks of nightly ecological momentary assessment surveys allow investigators to capture daily fluctuations in affect, craving, and smoking behavior.
- Remote surveys allow assessments of the intensity and persistence of daily mindfulness practice.
- Employing a practice quit attempt, study investigators may now capture momentary experiences of nicotine craving as well as long-term persistence of smoking cessation in daily life as naturalistic observation.

Clinicaltrials.gov: NCT03819231

## References

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