Remote-based Group Treatment for Smoking and Alcohol use

Christine Vinci, PhD
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Department of Health Outcomes and Behavior

Society for Clinical Trials
May 2024

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Disclosures

- R34AT009689
- R01CA255265
- R01DA055298

Primary Aim

- To develop and pilot test a mindfulness-based group treatment to aid individuals in quitting smoking and modifying their alcohol use and compare results to cognitive behavioral therapy
- And because of COVID….
  - To determine the feasibility of delivery via telehealth

Contents lists available at ScienceDirect

Drug and Alcohol Dependence

journal homepage: www.elsevier.com/locate/drugalcdep

Pilot randomized controlled trial of mindfulness-based relapse prevention vs cognitive behavioral therapy for smoking and alcohol use

Christine Vinci [a,b,*], Steven K. Sutton [a,b], Min-Jeong Yang [a], Sana Baban [a], Rachel Sauls [a], Katie Witkiewitz [c], Karen O. Brandon [a], Marina Unrod [a], Thomas H. Brandon [a,b], David W. Wetter [d]

Design and Participants

- Two-arm RCT
  - Mindfulness-Based Relapse Prevention – Smoking and Alcohol (MBRP-SA)
  - Cognitive Behavioral Therapy (CBT)
- Examine feasibility and acceptability of MBRP-SA compared to CBT
- Changes in cigarette and alcohol use over time

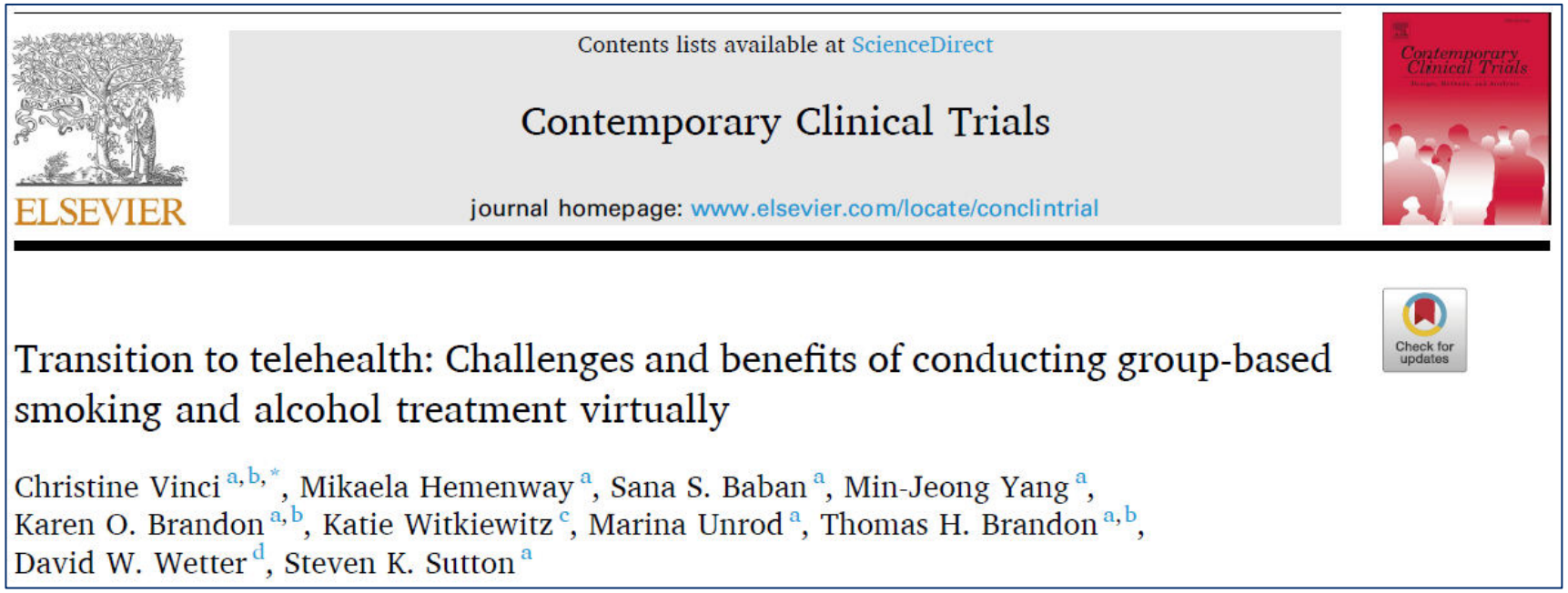
- Participants
  - ≥ 18 years of age
  - 3 CPD in past month
  - ≥ 1 binge drinking episode in past month
  - Motivated to quit smoking and modify alcohol use in next 60 days

Procedures

- Group sessions
  - 8 weekly sessions for 2 hours each
  - Zoom
  - Led by clinical psychologists
- Nicotine Replacement Therapy (patch) provided for 6 weeks
  - Started at week 5 (quit date)
- Assessments
  - Baseline
  - End of Treatment
  - Follow up 1 (5 weeks post-treatment)
  - Follow up 2 (8 weeks post-treatment)

Challenges and Benefits

- Participants
- Group facilitators
- Study staff



ELSEVIER

Contents lists available at ScienceDirect

Contemporary Clinical Trials

journal homepage: www.elsevier.com/locate/conclintrial

Transition to telehealth: Challenges and benefits of conducting group-based smoking and alcohol treatment virtually

Christine Vinci [a,b,*], Mikaela Hemenway [a], Sana S. Baban [a], Min-Jeong Yang [a], Karen O. Brandon [a,b], Katie Witkiewitz [c], Marina Unrod [a], Thomas H. Brandon [a,b], David W. Wetter [d], Steven K. Sutton [a]

Participants

Demographics (n=67 completed baseline)

Variable	M (SD) or %
Age	44.1 (9.5)
Female	69%
Sexual Orientation	81% Straight 19% LGBTQ
Race	64% White 27% Black/African American
Non-Hispanic	88%
Annual household income	72% had < $49,999
Education	28% HS diploma or < 72% Associates or >
Employment	58% Full or part time employed
Insurance	30% Uninsured

PROJECT RISE

This document is an **overview** of each visit and call.

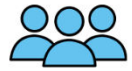
Zoom Orientation

Occurs one week before first visit .
The **group facilitator** will explain the process of using Zoom.

One week before your first visit.

SESSION 1
Automatic Pilot and Relapse

SESSION 2
Awareness of Triggers and Craving



SESSION 3
Mindfulness in Daily Life

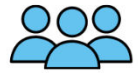
Phone Call

You will receive a phone call with a **staff member** to answer questions about your smoking and drinking.

Occurs **between visits 3 and 4.**

SESSION 4
Mindfulness in High-Risk Situations

SESSION 5
Acceptance and Skillful Action



SESSION 6
Seeing Thoughts as Thoughts

SESSION 7
Self-Care and Lifestyle Balance

Phone Call

You will receive a phone call with a **staff member** to answer questions about your smoking and drinking.

Occurs **between visits 7 and 8.**

SESSION 8
Social Support and Continuing Practice

Follow-Up Call

You will receive a phone call from a **staff member** to answer questions about your smoking and drinking.

You may be asked to complete an interview for give your feedback.

Five weeks after your last visit.

Follow-Up Call

You will receive a phone call with a **staff member** to answer questions about your smoking and drinking.

Eight weeks after your first follow-up call.

PROJECT RISE

This document is an **overview** of each visit and call.

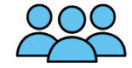
Zoom Orientation

Occurs one week before first visit .
The **group facilitator** will explain the process of using Zoom.

One week before your first visit.

SESSION 1
Reasons for Smoking and Drinking and Benefits of Quitting Smoking

SESSION 2
Identifying and Coping with High-RIsk Situations



SESSION 3
Preparing for Life Without Cigarettes

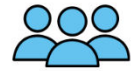
PHONE CALL

You will receive a phone call with a **staff member** to answer questions about your smoking and drinking.

Occurs **between visits 3 and 4.**

SESSION 4
Stress Management and Preparing for Quit Day

SESSION 5
Preparing for Success by Anticipating Challenges



SESSION 6
Continue to Identify High-Risk Situations and Coping Strategies

SESSION 7
Managing Weight Gain and Looking to Future Threats to Abstinence

Phone Call

You will receive a phone call with a **staff member** to answer questions about your smoking and drinking.

Occurs **between visits 7 and 8.**

SESSION 8
Preparing for Treatment End and a Smoke-Free Future

Follow-Up Call

You will receive a phone call from a **staff member** to answer questions about your smoking and drinking.

You may be asked to complete an interview for give your feedback.

Five weeks after your last visit.

Follow-Up Call

You will receive a phone call with a **staff member** to answer questions about your smoking and drinking.

Eight weeks after your first follow-up call.

Hello [insert name],

Thank you for participating in Project RISE! We are excited to have you as part of our study. In this packet, you will find study materials for your Zoom Orientation session scheduled on **[Date/Time]**. During the Zoom Orientation, the entire group will be present, and you will be asked to reference the included materials.

In this mailout, you should have received the following:

1. "How to Use Zoom" Packet
2. Meet the Team
3. Project Timeline
4. Session Handouts
5. Website Instructions
6. Headphones
7. [if in MBRP-SA]: Meditation CDs (4)
8. [if needed]: Tablet and USB Charger
9. [if needed]: "How to Use the iPad" Packet

If you did not receive any of the materials above, or if you have any questions, please call our study staff at (813) 745 – 4078.

Please remember to review the **"How to Use Zoom" Packet** for instructions on how to access your Zoom Orientation session. We look forward to talking with you!

Thank you,
Project RISE
Tobacco Research and Intervention Program (TRIP)
Moffitt Cancer Center
ProjectRISE@moffitt.org
(813) 745 – 4078

MEET THE TEAM

Marina Unrod, Ph.D. Dr. Unrod is excited to be your group facilitator over the next 8 weeks. Her background is in clinical psychology, and she has helped people change behaviors like smoking and alcohol use for 20+ years. She looks forward to meeting with you each week as you progress towards your quit smoking and alcohol modification goals!

Mikaela Hemenway, B.A., B.S. Ms. Hemenway is the research coordinator for Project Rise. You will be meeting with her for most of the assessments you complete during this study. She will also assist you with any technical issues that arise during group sessions. She looks forward to supporting your participation in this study! As a reminder, you can reach her during typical business hours at 813-745-4078.

Sana Baban. Ms. Baban is the research assistant for Project RISE. She will be assisting with the assessments you complete during the study. She may also assist you with technical issues that arise during group sessions. She looks forward to supporting your participation in this study!

Christine Vinci, Ph.D. Dr. Vinci is the principal investigator for Project Rise. She is thrilled to have you as part of this study and is hopeful that you will meet your goals! It is unlikely that you will interact much with Dr. Vinci, but she may help out along the way if needed.

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WEBSITE INSTRUCTIONS

During the study, you will have access to a website with all the study materials.

1. Open a web browser.
2. Enter the following link in the web browser: http://lab.moffitt.org/projectrisem
3. Bookmark the website on your browser for easier access.

On this website, you will have access to the Session Handouts, our "Meet the Team" page, the meditations, and our study contact information.

Project RISE

Session Handouts

YOUR STUDY SCHEDULE

This is an outline of your study visits. During your Orientation phone call, you will schedule visits with a study staff member. Use this sheet to write down the dates and times of your study visits and calls.

Zoom Orientation:_____

Visit 1:_____

Visit 2:_____

Visit 3:_____

Phone Call:_____

Visit 4:_____

Visit 5:_____

Visit 6:_____

Visit 7:_____

Phone Call:_____

Visit 8:_____

Follow-up Call:_____

Follow-up Call:_____

HOW TO USE ZOOM

For assistance, contact **Mikaela Hemenway,** at **(813) 745-4078.**

How to Use the iPad

For assistance, contact **Mikaela Hemenway,** at **(813) 745-4078.**

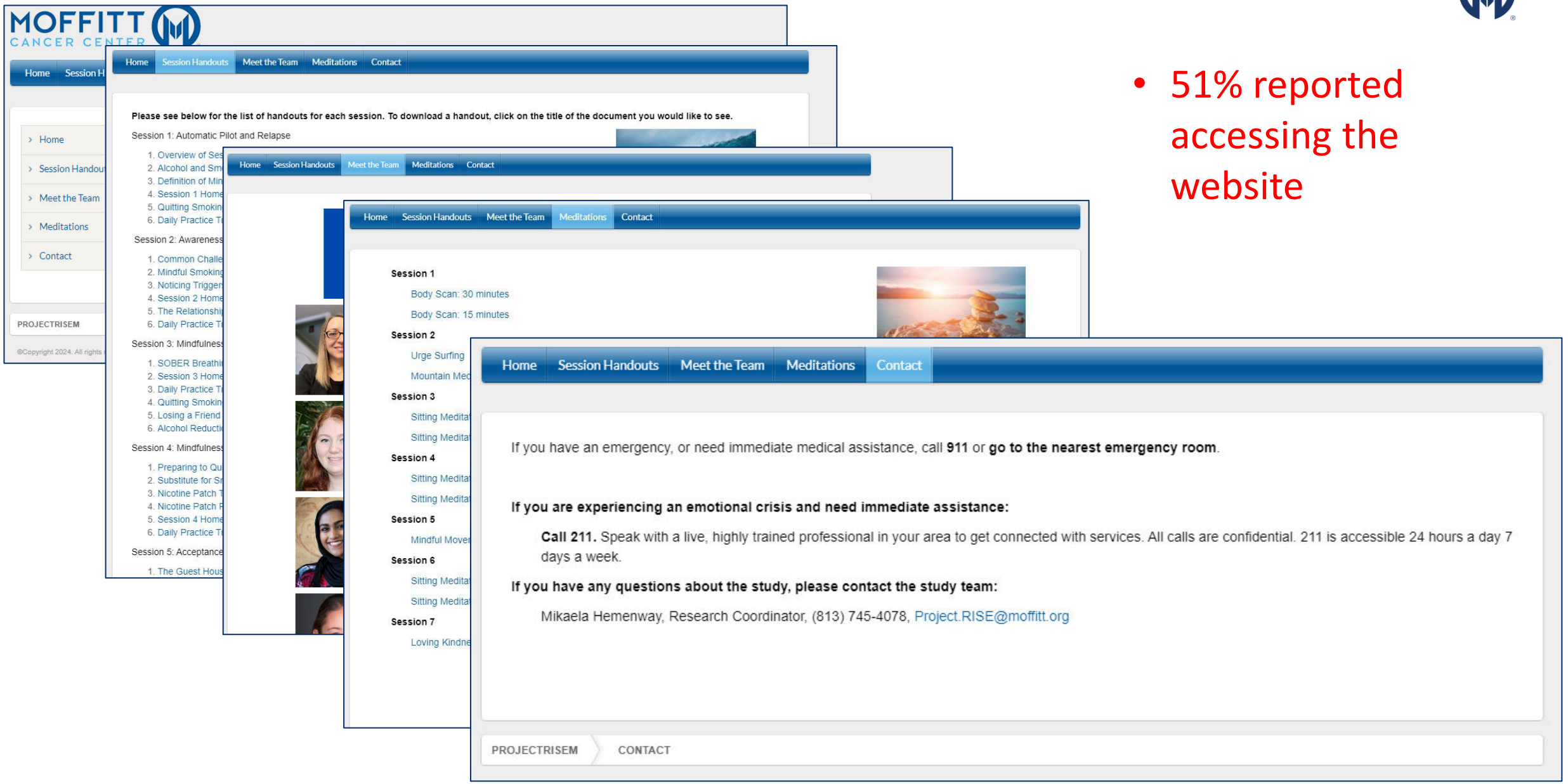
iPads

- Population is generally low socioeconomic status
- Concerns about engagement if attending Zoom sessions on smartphone
- Loaned tablets with camera and data plan
  - Zoom pre-loaded onto screen
  - Instructions for using Zoom on an iPad included
- Could use iPads for non-study related tasks
- Sent pre-paid FedEx box for tablet return
- 29% (20/69) of participants needed a tablet
  - 85% (17/20) tablets were returned

Orientation Session

- Group orientation scheduled 1 week prior to session 1
  - Zoom features (entering their name, using background, mute/unmute, camera on/off) practiced
  - Zoom etiquette (when to mute; privacy rules)
  - Participants introduced themselves to the entire group
  - Met the study team, including the group facilitator
- 70% (48/69) of participants attended the group orientation
- 97% of sample reported using a video conferencing app in the past
- Anecdotally, this session was very important to ensure participants could login to the Zoom sessions

Website



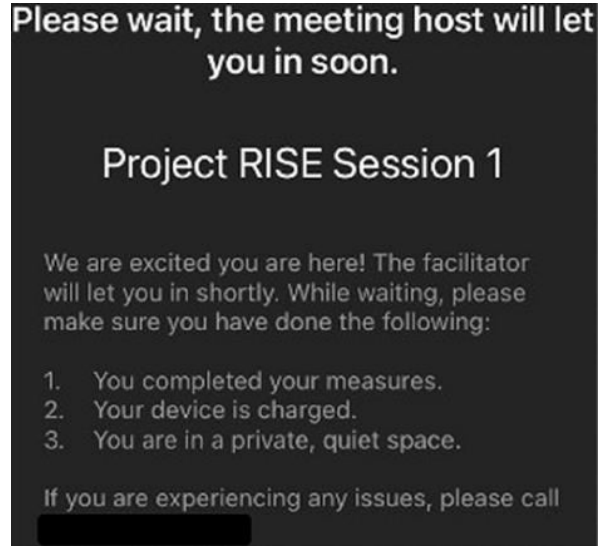
- 51% reported accessing the website

Sessions in a Private Location

- Protect confidentiality of participants
- COVID amplified this issue
  - More people in the home
- Small homes/limited private rooms
- Childcare/babysitter often not feasible

Sessions in a Private Location

1. At screening, we asked if it would be feasible for participants to secure a private quiet location for Zoom sessions
2. At zoom orientation, staff admitted participants one at a time to ensure they were in a private location
3. Waiting room screen before session served as a reminder
4. If another person appeared in the background during session, facilitator asked participant to relocate/leave call
5. Contacted participants between sessions to problem solve as needed



Interactions among Participants on Zoom

- In-person group sessions allow for more informal interactions among participants that likely facilitated group cohesion
  - Before, during, and after session chit chat
  - Handing someone a tissue, picking up a dropped item from someone, hand shaking
  - Mm-hmm, sighs in response to what someone said
- Encouraged people to stay unmuted during calls to help with flow of conversation and subtle verbal cues
- Invited participants to login a few minutes early to get to know each other better (rarely done)

End of Treatment Zoom Feedback

- 55% of participants reported contacting study staff for help with Zoom at least one time
- Increased comfort using Zoom over time (1=very difficult, 6=very easy)
  - Beginning of treatment: 4.8 (SD=1.5)
  - End of treatment: 5.5 (SD=1.1)
- Most useful zoom features
  - Screen sharing (endorsed by 51%)
  - Poll questions (35%)

Group Facilitators

Experience and Training

- Two clinical psychologists with experience running groups for substance use populations
- Never delivered treatment via Zoom
  - Attended Zoom training offered by our institution
  - Internal meetings with study team to problem solve
  - Between cohorts met as a group to determine how to better address technology issues with the next cohort

Challenges

- Another person appearing in the background (often a child)
  - Interrupt group to address
- Lengthy zoom sessions
  - Brief break at midpoint of session
  - Utilization of zoom features to keep sessions interesting (poll question, whiteboard, screen sharing)
    - Used sparingly though because these would block participants and facilitator from seeing each other
  - Breakout rooms
- Tiles reshuffling

Challenges

- Unable to pick up on nonverbal cues that indicate confusion, disagreement, or disengagement
- Brief check-ins with participants 1:1 challenging (medication concerns, arriving late to group)
  - Ask people to stay briefly after group session (awkward in group)
  - Have a separate phone call to discuss
  - At orientation communicate to entire group that facilitators may ask people to stay on after session to briefly check-in

Study Staff

Zoom Sessions

- Staff member present on each Zoom session
  - Staff vs group facilitator roles outlined at orientation session
- Recorded sessions
- Setup Zoom calls with needed features (waiting room screen, poll questions)
- Contacted participants with tech issues
  - Usually during the session itself

Preparation and Delivery of Study Materials

- Time intensive and recommend a specific timeline for all mail outs
- Overnight delivery and tracking to ensure prompt arrival
- Maintain connection with participants between consent and first session with carefully planned mailouts
- Clear, concise instructions appeared on all study documents

Benefits

Participant Benefits

- Reduced time and costs associated with attending sessions
- Transportation issues due to inconsistent public transportation or inclement weather
  - Group sessions unable to be rescheduled, so perhaps most important for this type of delivery modality
- Easier to arrange childcare (more so for older children)
- Working from home allowed quicker access to login to zoom (vs driving to session)
- Cognitive effort associated with planning travel and locating facility removed
- Concerns about intoxicated individuals traveling to/from session eliminated

Group Facilitator Benefits

- Group disruptions minimized (vs in-person)
  - Late arrivals, mute if someone is noisy, turn off video feature
- Staff member always on sessions– allowed facilitator to completely focus on treatment content
  - Technology concerns, compensation, NRT issues

Study Staff Benefits

- Communication about study-related issues with staff present in Zoom sessions allowed staff to more easily address problems (e.g., NRT)
- Greater rapport building due to increased contact for technology issues, mailouts, etc., which likely supported retention
- Recruitment more feasible with remote-based studies
- No need to reserve rooms for session or figure out parking for participants
- For in-person sessions we often arranged security for evening groups, which was not needed for Zoom sessions

Thank you!

Co-Investigators

- Katie Witkiewitz, PhD
- Tom Brandon, PhD
- David Wetter, PhD
- Steve Sutton, PhD

Group Facilitators

- Karen Brandon, PhD
- Marina Unrod, PhD

Study Staff

- Mikaela Hemenway, BS
- Sana Baban, BA
- Rachel Sauls, BA
- Amanda Farris, LCSW

Other

- Min-Jeong Yang, PhD (postdoc)
- Study participants
- Undergraduate interns

Remote data collection methods in smoking- and weight-focused trials

Cara Murphy, Ph.D.

Center for Alcohol & Addiction Studies, Brown University

45th Annual Meeting of the Society for Clinical Trials (SCT)

Boston, Massachusetts

May 20, 2024

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Center for Alcohol & Addiction Studies

Disclosures

- Funding: This work is supported by
  - The National Institute on Drug Abuse (NIDA)
  - The National Institute of General Medical Sciences (NIGMS)

- I have no conflicts of interest to report

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Risks from smoking **AND** obesity

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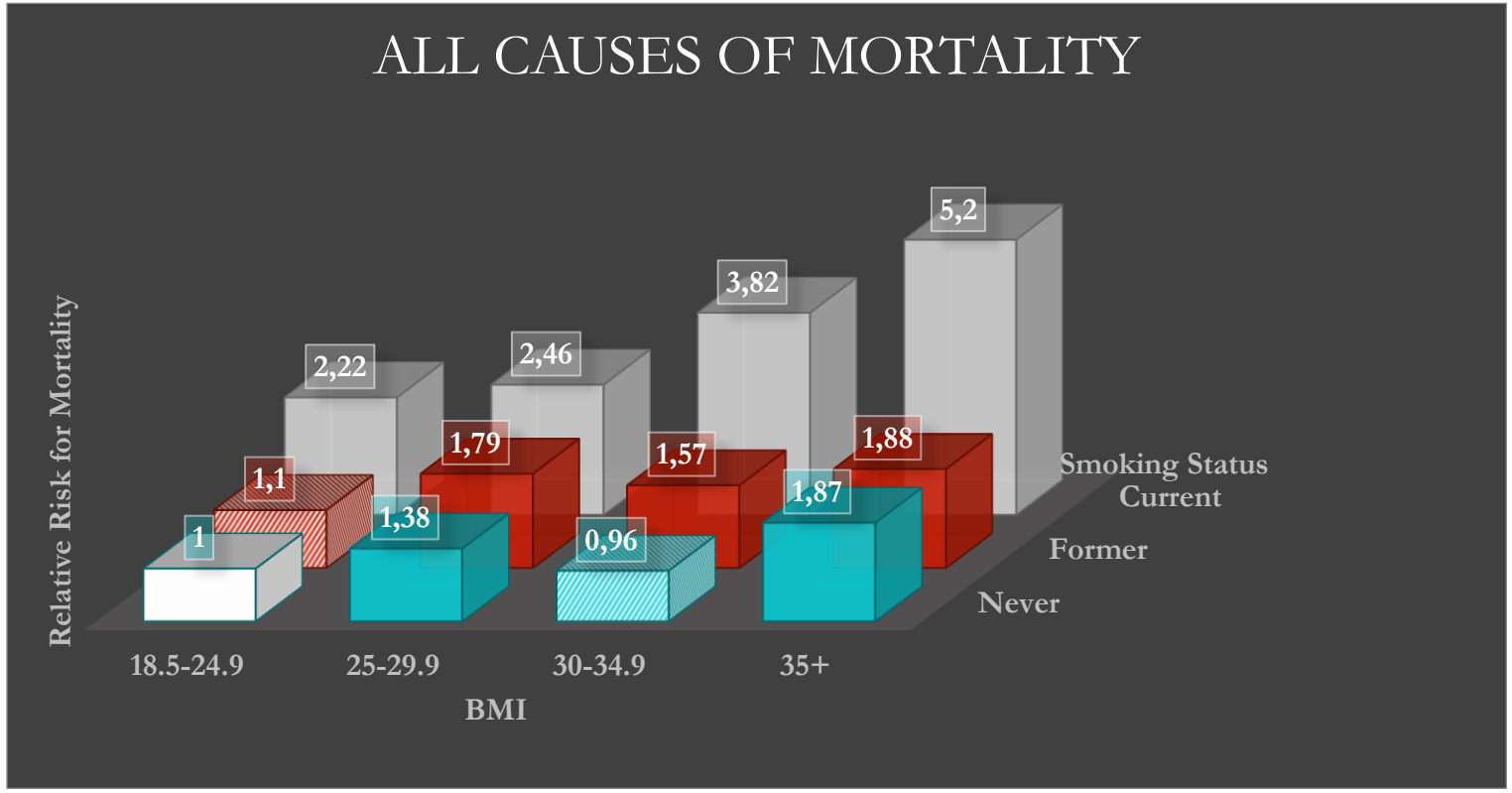

FREEDMAN ET AL., 2006
DOI: 10.1016/J.AMEPRE.2006.07.022

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Study 1

A Multiple Health Behavior Change Intervention for Individuals with Overweight or Obesity who Smoke Cigarettes

Why Target Multiple Behaviors?

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- People are multidimensional
- ↑ health gains/benefits
- ↓ health risks & healthcare costs
- Capitalize on momentum & self-efficacy
- Efficiency (esp. if change process is similar)
  - Intervene on common underlying factors (e.g., impulsive decision making)
  - Teaching effective behavior change principles and coping strategies (e.g., self-regulation)
  - Potential for widespread change in MHBs
- Missed opportunity to target one health-compromising behavior but leave another unaddressed!

Prochaska & Prochaska (2011); Prochaska, Prochaska, & Prochaska (2018)

Eligibility Criteria

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- Smoke 5+ cigarettes/day
- BMI 25+
- Age 18-75
- Some motivation to quit smoking and prevent weight gain (4/10)
- Not in smoking cessation or weight management treatment
- Minimal use of other nicotine & tobacco products
- No clinically relevant medical or psychological condition that would interfere with participation (e.g., inability to use NRT products, contraindicated medications, pregnancy)

Patient-Centered Approach

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- Wanted the intervention to be guided by the opinions, values, and experiences of those it was being designed to help
- Designed a **in-person** intervention and planned to start recruitment in Spring 2020….

Eating Behaviors 53 (2024) 101883

ELSEVIER

Contents lists available at ScienceDirect

Eating Behaviors

journal homepage: www.elsevier.com/locate/eatbeh

"Healthier health in more ways than one": Perspectives on a program for changing both smoking and obesity-related health behaviors

Cara M. Murphy [a,*], Kelli Scott [a,1], Suzanne M. Colby [a,b], Julia Yermash [a,1], E. Whitney Evans [b,c], Rena R. Wing [b,c], Liza A. Kolbasov [a], Damaris J. Rohsenow [a]

[a] *Center for Alcohol and Addiction Studies, Brown School of Public Health, Providence, RI, USA*
[b] *Department of Psychiatry and Human Behavior, Alpert Medical School of Brown University, Providence, RI, USA*
[c] *Weight Control & Diabetes Research Center, The Miriam Hospital, Providence, RI, USA*

GET FIT TO QUIT

Design

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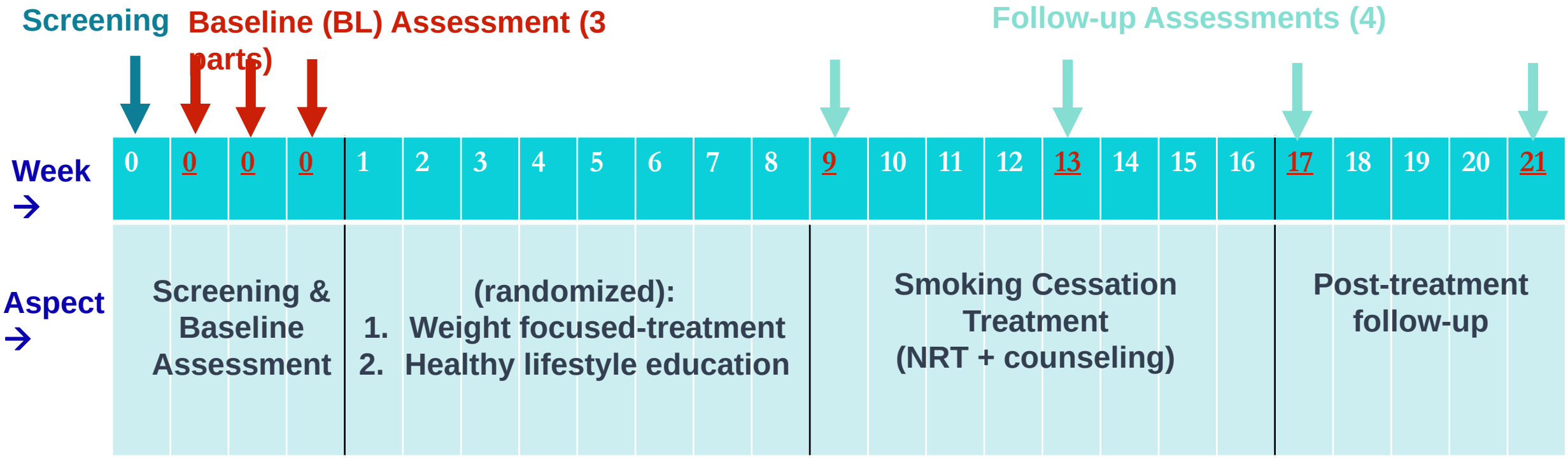

- **Main study outcomes:**
- **1) feasibility & acceptability; 2) smoking/abstinence; 3)weight**

Assessment Sessions

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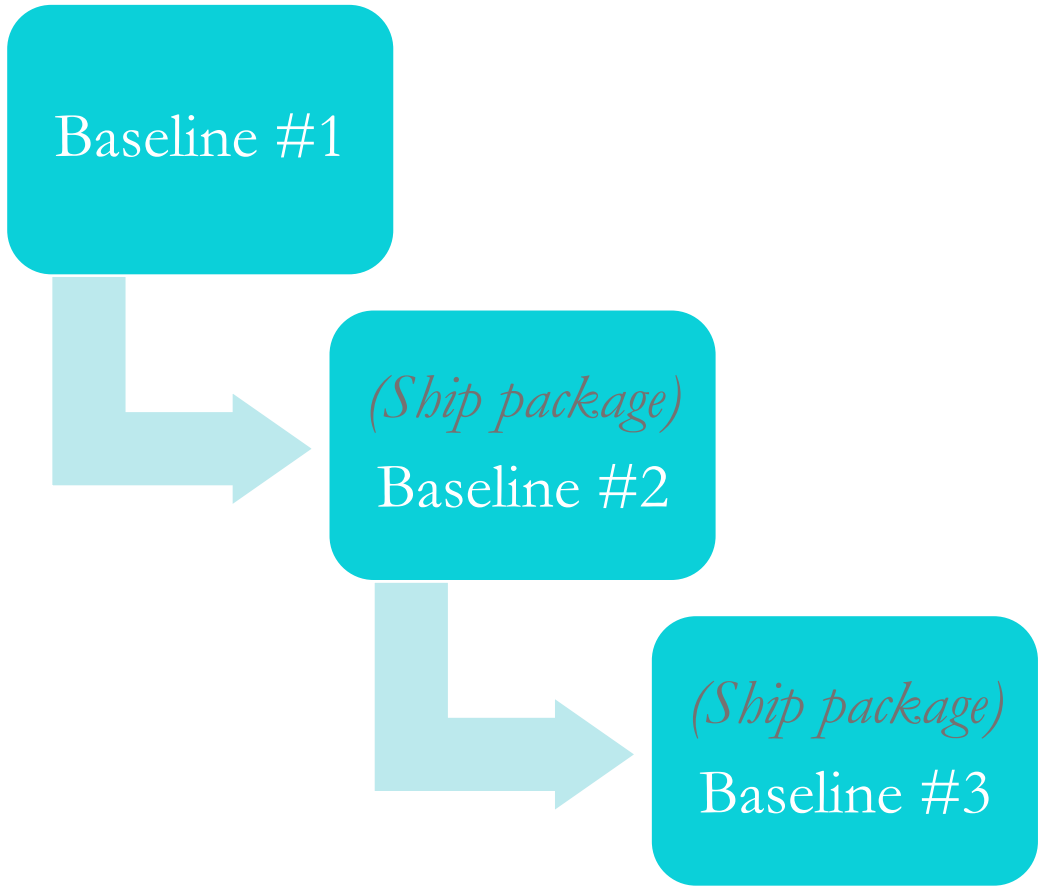
- Research-Assistant Facilitated (Zoom)
- Baseline session #1
- *Electronic questionnaires*
- *Interviews*
- Baseline session #2 & #3
- *Biophysiological measures*



Saliva Cotinine Test

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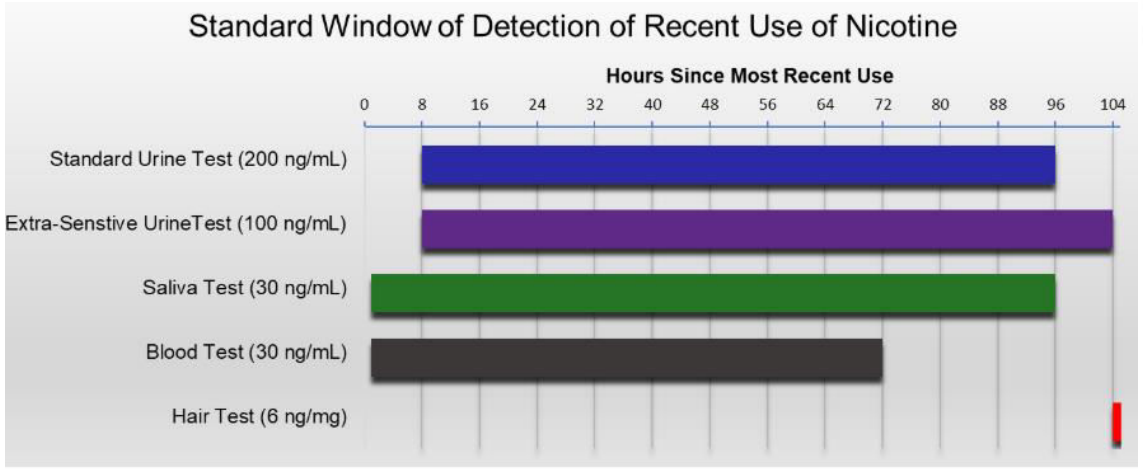
- NicoTests™ Saliva Cotinine Test
  - Cut-off 30 ng/mL
  - ~$3.50/test
- Methods
  - RA guided/observed (Zoom)



GET FIT TO QUIT

Results using NicoTests

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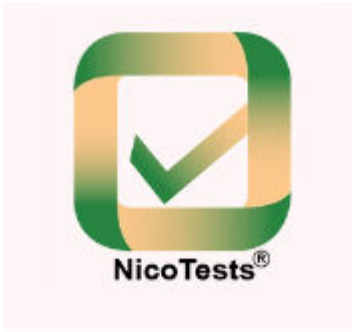
- 119 participants eligible for baseline assessment (based on screening)
- 12/119 (10%) did not attend baseline assessment #1
- 30/119 (25%) deemed ineligible baseline assessment #1
- 77/119 (65%) scheduled for NicoTest & weight **(baseline assessment #2)**
    - 5/77 (6%) never attended 2nd session
    - 2/77 (3%) had inconclusive test results and unable to repeat the saliva test
    - 5/77 (6%) had negative test results (level of cotinine below threshold)
    - 65/77 (84%) had positive test results (level of cotinine indicative of nicotine/tobacco use)



Saliva Cotinine Test

- **Pros**
  - High acceptability & ease of use
  - Relatively low cost
  - Results in 10 minutes
- **Cons**
  - Occasional participant challenges (e.g., dry mouth, unable to collect enough saliva for test to run)
  - Invalid/inconclusive results
  - Delays due to multi-session baseline protocol
  - Can’t isolate smoking from other nicotine/tobacco use

iCOquit® Smokerlyzer®

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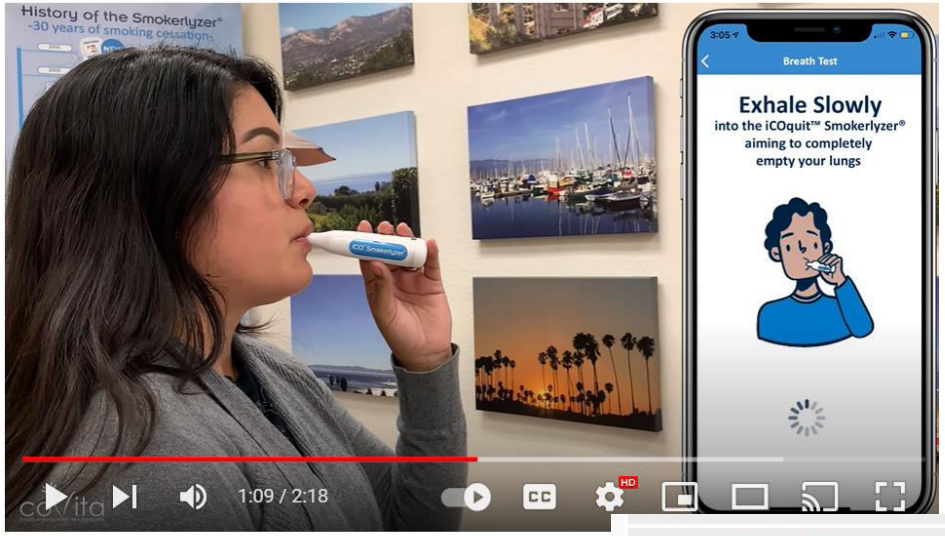
- Exhaled carbon monoxide monitor connects to Bluetooth enabled device
- Methods
  - RA guided/observed (Zoom)
  - Repeated measures for reliability
  - *Advertised accuracy of ±≤3 ppm*
- Cost $65/monitor + shipping



Introducing iCOquit™ Smokerlyzer®

coVitaLLC
49 subscribers
Subscribe


Select breath test icon on the dashboard.


Connect the iCOquit® device.


Inhale and hold your breath for 15 seconds.


Slowly exhale in to the iCOquit®.

Instantly see results with option to share.


Track your success using interative chart.

Results using iCOquit

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- 60 participants completed **baseline #3**
- 55 randomized
- *95% of participants or greater completed follow-up at each timepoint*
- Compensation for completing ALL assessments = $230 (max)

	Baseline #3	Follow-up #1 (mid-txt)	Follow-up #2 (1 mo post-quit)	Follow-up #3 (2 mo post-quit)	Follow-up #4 (3 mo post-quit)
N (%) completing	60/65 (92%)	53/55 (96%)	53/55 (96%)	52/55 (95%)* *50 w/ CO data	52/55 (95%)* *50 w/ CO data
Association between 1st & 2nd reading	$r = .85$	$r = .99$	$r = .96$	$r = .95$	$r = .95$
% of pts with 1st & 2nd reading ≤3 ppm apart	40/60 (67%)	49/53 (92%)	49/53 (92%)	43/50 (86%)	42/50 (84%)

Results using iCOquit

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- 7-day point prevalence abstinence =
- *Self-reported no smoking in past 7 days*
- *Biochemically confirmed abstinence ≤ 6 ppm.*

	Follow-up #1 (mid-txt)	Follow-up #2 (1 mo post-quit)	Follow-up #3 (2 mo post-quit)	Follow-up #4 (3 mo post-quit)
N (%) reporting abstinence	6/53 (11%)	32/53 (60%)	28/50 (56%)	28/50 (56%)
N (%) reporting abstinence, confirmed by CO	6/53 (11%)	26/53 (49%)	22/50 (44%)	23/50 (46%)

Acceptability (research staff)

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From session notes:

“Could not get iCOquit device to connect to iPhone 7 or iPad. We 1) made sure the Bluetooth and location were on, 2) held down the device power button for at least 10 seconds, 3) went to the app settings and turned everything off and then back on, and 4) restarted the phone as well. We tried this for about 30 minutes and neither of us could figure it out. The light would not turn on at all for the device.”

“My experience working with the iCOquit is that it is sort of unpredictable. When it works it’s fine…the time I’m always crossing my fingers is when it’s time to reconnect for the second or third test.”

iCOquit® Smokerlyzer®

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- **Cons**
- Can be somewhat costly (device and shipping costs, including replacements)
- Participants may lose or not have access to it the day of session or it may not work (Bluetooth connecting problems, damaged)
- Participants may struggle to hold their breath the full time
- Participants may become frustrated with taking more than one measurement at a time (especially if it becomes overly time consuming)
- Often a good bit of initial training and trial and error needed to set-up
- Can be impacted by other types of smoking

iCOquit® Smokerlyzer®

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- **Pros**
- Can assess smoking/abstinence rather than just nicotine use
- Can get results relatively quickly in the app with or without a research assistant to guide use
- Although there is a bit of a learning curve initially, participants (and staff) usually get the hang of over time with more reliable results obtained more readily
- Some participants report using it regularly as a way to monitor changes in their smoking/health

Body Weight

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- Used Etekcity digital scale
- Observed measurement
- Repeated for reliability
- Holds up to 400 lbs (180 kg)
- Cost $20/scale + shipping

Body Weight

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- **Pros**
  - High acceptability & ease of use
  - Low cost
  - Results in seconds
- **Cons**
  - Some participants may feel uncomfortable (same as in-person)
  - Only get weight data when shared by participants directly

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Study 2

Trial for Harm Reduction with Incentives & Vaping E-cigarettes

Study 2 (in brief)

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- Center for Addiction and Disease Risk Exacerbation (CADRE)
- Part of a larger NIH Center of Biomedical Research Excellence (COBRE) Grant
- CADRE is multi-disciplinary center to investigate bio-behavioral mechanisms by which substance use increases the risk for or exacerbates chronic disease
- Aims to harmonize across many projects to create a center-wide data repository

CENTER FOR ADDICTION AND
cadre
DISEASE RISK EXACERBATION

Collecting Additional Measures

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- Incorporating what we've learned (e.g., 2 BL sessions)

- Blood pressure
- Pregnancy testing
- Waist and hip circumference
- Blood collection (planned)

- Ease of recruitment/retention remains high!

Key Considerations

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- Will the participants do something once? More than once?
- What are the costs?
- How shipping/logistics be handled? How much of your time will this take?
- How can measurement error be minimized?
- How often will data be reviewed?

Takeaways!

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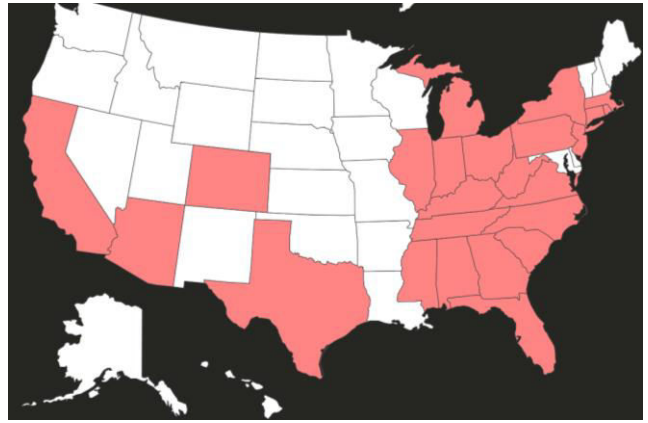
- Remote data collection for smoking and weight outcomes can bring challenges and costs and is not perfect
- **AND YET**
- It can be a powerful tool
- Participants and staff generally find procedures acceptable (and learn “tricks” over time)
- Can help eliminate barriers associated with in-person research
  - Allow for a more representative sample and greater retention and less missing data
- Provides greater assurance of study outcomes than could be achieved using self-reported only



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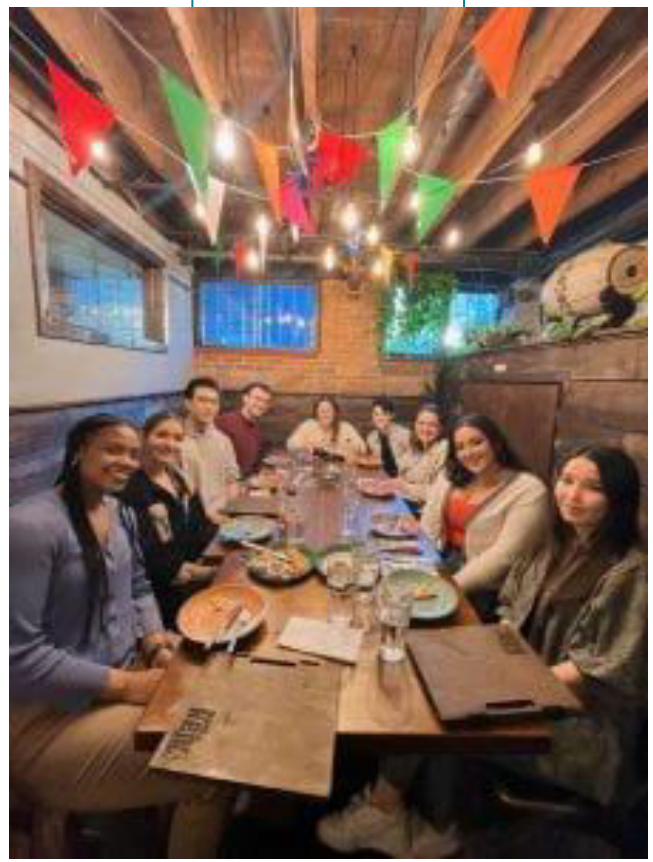
- Study Interventionists & Research Assistants
- Brown University support staff
- Research participants



MURPHY BROWN LAB

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Please feel free to contact me

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Case series of participant deception and protocol updates in an ongoing fully remote-trial

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2024 BOSTON
SCT | 45TH ANNUAL MEETING

Disclosures

- None.

Presentation overview

- Brief description of the ON-DEQ Study.
  - Background, design, aims, eligibility, study process.
- Deception experienced to date.
  - Common issues, protocol changes implemented.
- Presentation of a few memorable cases.
- Concluding remarks.

Background

ON-DEQ Study

Overcoming Nicotine Dependence to Enable Quitting

RUSH

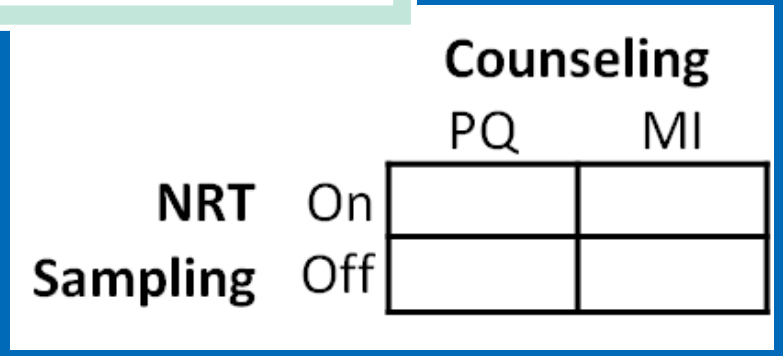
Most smoking cessation programs are centered on a set quit date

- Smokers are not ready to quit in the next month, and motivation to quit changes rapidly.
- Strategies for all tobacco users, across a continuum of motivation to quit, are greatly needed.

Practice quitting (PQ)

- Attempting not to smoke for a few hours or days, without any pressure or expectation to permanently quit.

Trial design



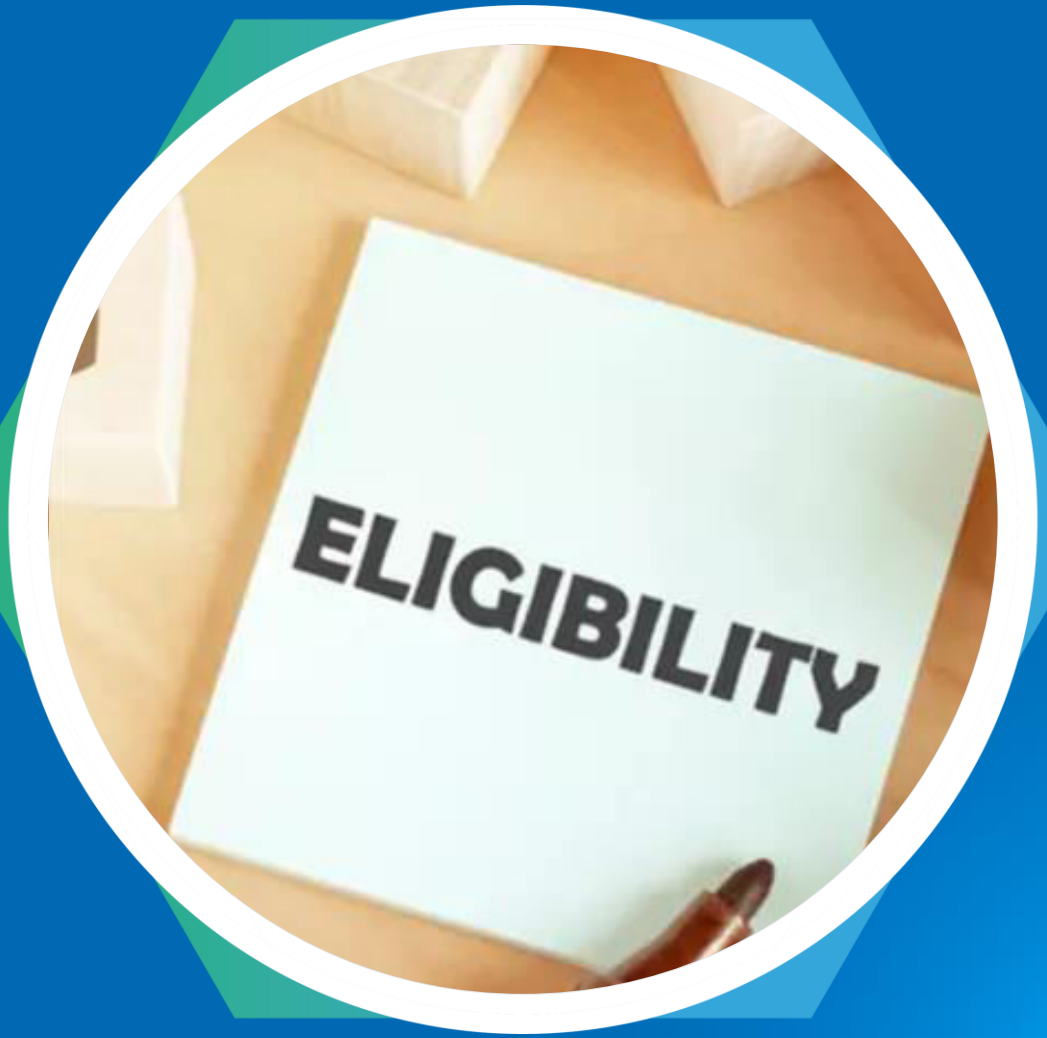
- Trial is conducted fully remotely.
- 2 x 2 factorial design.
  - N=780, n=195 per cell.
- Factor 1 – Counseling.
  - PQ-focused behavioral treatment to foster nicotine withdrawal exposures through “practice quitting” exercises.
  - Vs. Motivational interviewing (MI).
- Factor 2 – NRT sampling.
  - Nicotine patches & lozenges on a temporary or trial basis.
  - Vs. none.

Trial aims and outcomes

- Aim 1: Evaluate hypothesized treatment mechanisms on incidence of permanent quit attempts at 6 months.
- Aim 2: Test the individual and combined roles of behavioral counseling and NRT sampling on quit attempts and cessation at 6 months.
- Primary outcome: Permanent quit attempt defined as intentional abstinence of ≥24 hours since end of treatment at 6 months.
- Secondary outcome: Abstinence status at 1, 3, 6-months, self-report of no smoking in past 7 days confirmed with a CO monitor.

Inclusion and exclusion criteria

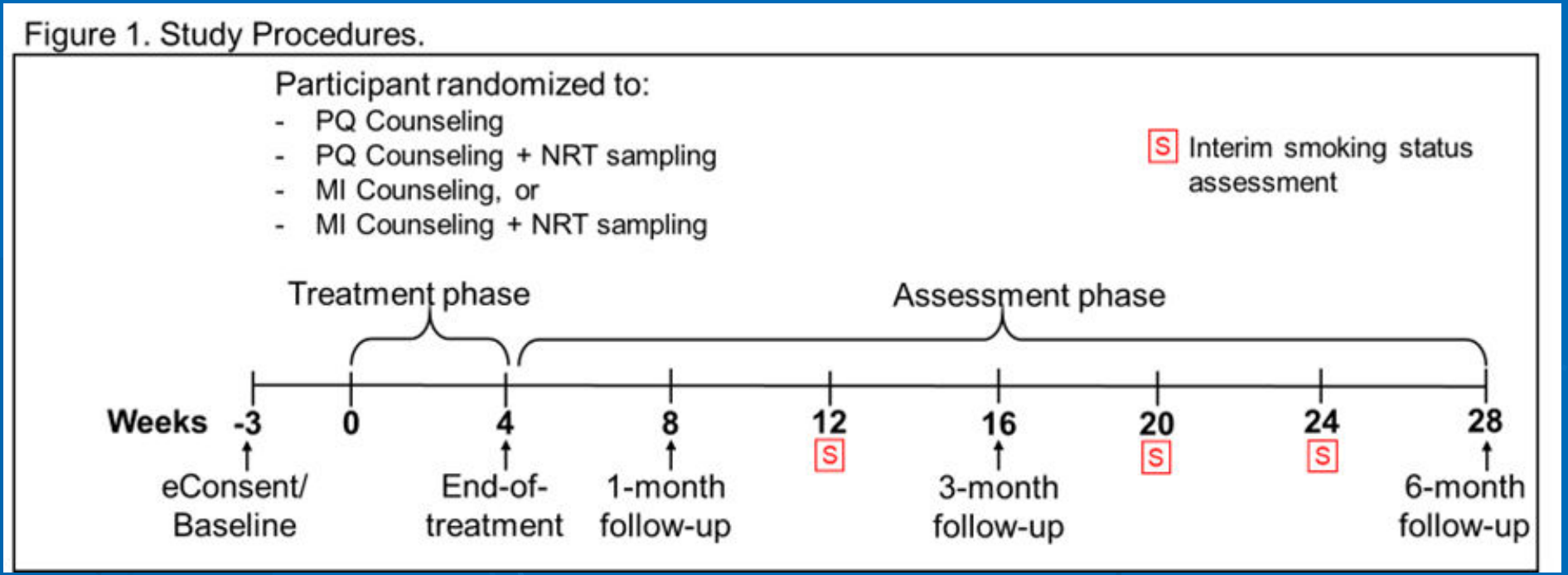
- Inclusion:
  - Age ≥18.
  - Currently smoking ≥5 cigarettes / day.
  - Not planning to quit in the next 30 days.
  - Not undergoing cessation treatment.
  - Motivated to quit smoking.
  - English speaking.
  - Resides in continental US.
  - Access to a smartphone.
- Exclusion:
  - Daily vaping or e-cigs.
  - Any counterindication for NRT.



Recruitment procedure

- Nationwide online recruitment through social media, e.g., Facebook.

- Original protocol:
  1. Potential participants click study ad to fill out a 5-min. pre-screener.
  2. Eligible persons do a phone call screening by staff to confirm interest/eligibility.
  3. E-consent through REDCap and baseline assessment.
  4. Randomization.
  5. Mail CO monitor and intervention material.



Study compensation

- Week 0 ($40): Received study package, CO monitor.
- Week 4 ($30): Fully assessment battery but no CO.
- Weeks 8, 16, 28 ($40 each): Fully battery with CO.
- Weeks 12, 20, 24 ($20 each): Only smoking status.

- Total compensation for completion is up to $250.

Issues with deception

- Guided by the literature on remote trials, we expected a certain degree of deception and ingenuine attempts to join our study.
  - Initial set of systematic procedures were in place before recruitment began.
  - E.g., using REDCap to check for duplicate pre-screener submissions.

- We quickly realized; however, some were very "creative".
  - Necessitated protocol modifications.
  - Requires ongoing monitoring and constant adaptation.

- Almost all cases are with respondents providing false information.
  - A person using false information to try to get into the study.
  - A person trying to get into the study multiple times using different identities.

Issue 1: Is that really you?

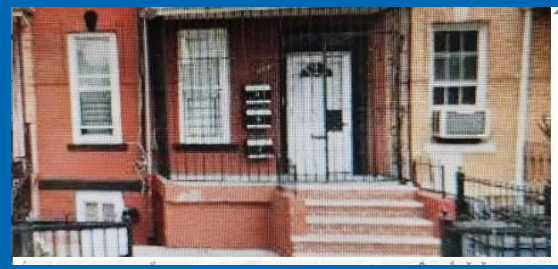
- Falsification of their name and age are most common.
- How we check:
  - True People Search.com – name should match city/state of their address.
  - Two first names, e.g., "Jay Michael".
  - Common family name but as first name, e.g., "Miller Paul".
  - Nicely rounded age, e.g., 25, 30, 35, etc.
  - Ask for ID – only for very suspicious cases that cannot be ruled out.

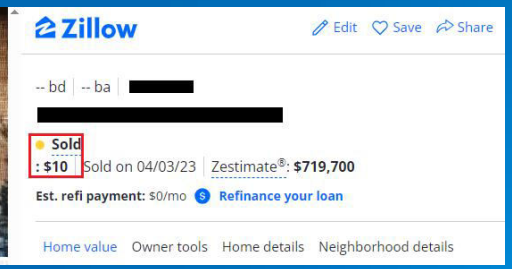
- Smoking ≥5 cigarettes / day is an inclusion criterion.
  - Multiple pre-screeners with different smoking amounts (until eligible).
  - Drastically different answer from pre-screen vs. phone screen.

Issue 2: Not in the US

- An inclusion criterion is to live in the continental US.
  - Counselors work regular business hours.
  - Must mail study package in a timely fashion
  - State of residence asked on pre-screener.

- How we check:
  - True People Search.com – should match the city and state on address.
  - FedEx online form – address should be a valid in their system.
  - REDCap – records both local server time and respondent's local time.
  - Zillow.com – look for anything strange.

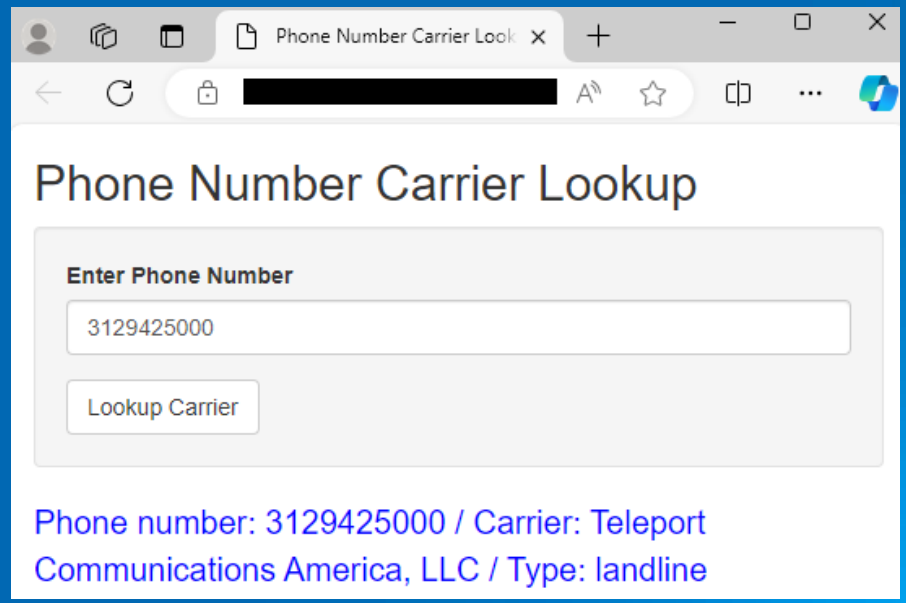




Issue 3: No valid cell number

- Having a smartphone is an inclusion criterion.
  - Coupled with the US residency criterion, we would assume they would have a valid US phone number.
  - Handful of respondents have had Google Voice numbers.
  - Not inherently a problem, but these usually corresponded with other "red flags".

- How we check:
  - Voice mail for Google Voice has a distinct message.
  - We use Twilio to send automatic text reminders.
  - An API for Twilio looks up carrier's name.
  - We built a R shiny app to match number to carrier.



Protocol changes

- Implemented a second online pre-screener.
  - One day after screening eligible for the original pre-screen.
  - Before they get a phone call screening.
  - Asks the respondent to verify their name, phone, address, DoB, email.
  - "Professional participants" tend to use multiple contact information; they may not remember what they entered yesterday.

- Required a valid US cell phone number.
  - Voicer-over-Internet-Protocol (VoIP), e.g., Google Voice, are not allowed.

Case 1 – pick a city any city

- Male, early to mid 30's, indicated that he is non-Hispanic White.
  - Provided a Google Voice number (prior to protocol modification).
  - Spoke with a West African accent.
  - Gave mostly one-word answers such as "yes" or "mmhm".

- Suspicious, staff asked where in Texas he lived.
  - Unnaturally long pause.
  - After, he said with the conviction of a fifth grader guessing on a geography exam, "uuhhh … Houston? Yeah, Houston Texas."
  - Proceeded to spell Houston out loud.

- He was screened out before the e-consent.

Case 2 – Victor/Victoria

- “Victor” indicated gender is male on the pre-screener.
- When study staff called, someone with a female voice answered, but switched to a deeper voice after the staff identified herself. Voice switched numerous times during the call.
- Email provided is listed as “Victoria”.
- Although strange, we have no exclusions based on gender, and everything else checked out. Thus, they were randomized and still in the study.

Case 3 – went to the well once too often

- Male participant, got through screening and was randomized.
- Before the first counselling session, he submitted another pre-screener with a different identity.
- Caught because for his second screener, he listed his cell number from the first time as his alternate contact number.
- He was administratively withdrawn.
  - Deception was egregious and with intent.
  - Could not trust any of his baseline data.

Strategies are working

- A recent ON-DEQ Facebook ad had the following reply comment:
  - “This study makes you go through hoops to verify your identity.”

- Has not compromised trial rigor.
  - As of 5/16/2024, we have randomized N=205 participants in a little over one year.
  - Roughly 80% attendance on counselling sessions.
  - Follow-up assessment completion rate is over 90% for all time points.

Thank you!