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ORIGINAL ARTICLE

Feasibility of and reactivity to ecological momentary assessment (EMA) during electronic cigarette use initiation in adults who smoke daily

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Abstract
Background and objectives: This pilot study tested the feasibility of tracking e-cigarette initiation over three months using a burst-of-measurement approach and examined reactivity to the ecological momentary assessment (EMA) data capture technique in this context.
Methods: Adults who smoked daily and were interested in trying e-cigarette use received an e-cigarette starter kit and were randomized to complete EMA reports ($n = 30$) vs. not ($n = 29$). Participants (M_{age}=44.1 years [SD=12.6], 61.0 % male, 54.3 % White, 38.9 % Black/African American) smoked 13.0 cigarettes per day on average (SD=8.4) and reported mild-to-moderate nicotine dependence (M_{FTND}=4.0 [SD=2.3]). Biochemical assessment and surveys were conducted at enrollment, e-cigarette initiation (1 week later), and 1-week, 1-month, and 3-month post e-cigarette initiation.
Results: A subset (17 %) of participants did not achieve the minimum 75 % EMA adherence at Week 1. The remaining participants showed excellent adherence with the EMA protocol, with a consistently high response rate to audibly prompted mini-surveys during screening (93 %) and follow-up weeks (93 %, 93 %, and 92 %, respectively). No consistent trend emerged in comparing the two randomized groups, either on variables relevant to the public health impact of e-cigarette initiation (i.e., cigarettes/day, exposure to smoke, exposure to nicotine, motivation to

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quit smoking), or in e-cigarette use (i.e., bouts/day, puffs/bout), with average Cohen's *d* values across timepoints ranging from *d* = 0.02 for exposure to smoke to *d* = 0.06 for cigarettes per day. *Conclusions:* Conducting EMA with adults who smoke daily and are initiating e-cigarette use appears feasible, with some caveats. Reactivity to EMA during e-cigarette initiation appears to be small or non-significant.

Electronic cigarettes (e-cigarettes) are nicotine delivery devices that have demonstrated remarkable uptake worldwide in recent years. The WHO, FDA, as well as the United States Surgeon General have made urgent calls for more research on e-cigarettes.[1-3] Despite concerns about health risks, from January 2017 to March 2022, the total monthly e-cigarette unit sales increased by 293.6 % to 23.3 million units and sales of products containing ≥5 % nicotine strength increased by 1486.3 %, representing 80.9 % of all e-cigarette sales.[4] Ecological momentary assessment (EMA)[5] is a data capture technique that samples experiences and behaviors as they occur in real life. Thus, this methodology can provide critical insight into how people who smoke use e-cigarettes.

One worry in using EMA, however, has always been the potential of reactivity to frequent assessments, that is, the possibility that answering EMA questions will cause meaningful — and potentially negative — changes in behaviors, thoughts or feelings. In some instances, EMA reactivity is the goal of repeatedly asking about a behavior and its context. For instance, in EMA-based clinical interventions, behavioral or psychological experience monitoring or prompts to engage in behaviors based on EMA data are meant to change behavior.[6] The goal would be for a patient to develop insight into their behavior based on repeated measurement of that behavior and its context, thereby increasing their ability to change that behavior. Studies to date, however, have typically shown non-significant effects of EMA on targeted behavioral outcomes, and only modest effects on related psychosocial constructs.[7,8] These results suggest that measuring behaviors with EMA does not systematically change established behaviors under investigation.

Behavior *change* could be one process whereby EMA shows meaningful influence on behavior and specifically on smoking. During behavior change, the behavior of interest and related constructs are in flux, and thus are potentially more vulnerable to outside influences such as EMA. Three studies to date have addressed EMA reactivity in the context of behavior change by testing the impact of EMA on people who smoke undergoing a quit attempt.[8-10] Compared to no EMA reports, Rowan and colleagues[9] found that one week of EMA reporting prior to planned quit dates had no effect on smoking abstinence rates 7 and 28 days later (*N* = 96). Group differences did exist, however, on 7-day and 28-day outcomes of the 20 assessed subscales of self-efficacy and withdrawal, but patterns were inconsistent. To estimate the impact of the duration of EMA reporting, McCarthy and colleagues randomized participants (*N* = 70) to complete EMA reports during 4 versus 7 weeks leading up to a quit attempt as well as during 3 weeks following the quit attempts, and found no group differences in withdrawal symptoms during the 6 overlapping weeks.[10] To estimate the impact of EMA intensity, McCarthy and colleagues[8] randomized participants (*N* = 110) to complete one versus six EMA reports per day over a period of four weeks, with EMA assessments beginning one week prior to smoking cessation, and ending three weeks following smoking cessation. They found no impact of EMA on smoking cessation or prolonged abstinence over a period of 10 weeks. This study did, however, show lower craving, anxiety, anger, hunger, and positive affect in participants randomized to the high-frequency EMA condition. Taken together, these studies provide evidence that EMA reporting is unlikely to impact conventional smoking behavior outcomes, even during a period of behavior change, but that it may impact constructs relevant to smoking cessation.

Three studies to date have reported EMA data on e-cigarette use, to our knowledge.[11-13] Though these studies help understand the context of dual use of cigarette and e-cigarette use among established dual users, no studies to our knowledge to date have examined e-cigarette *initiation*, nor have they reported on potential EMA reactivity. In addition, both Huh and Camenga focused on dual cigarette and e-cigarette use in young adults,[11,12] who may have different e-cigarette habits relative to established adults who smoke. In addition, these three studies[11-13] collected EMA data for 7 to 14 consecutive days, which does not capture whether e-cigarette use, cigarette use, and their context change over longer periods of time.

Given the demonstrated usefulness of EMA in smoking research,[14,15] and increasing calls for research on e-cigarettes,[1-3] we extended previous work and conducted a pilot study to test the feasibility of using EMA to capture e-cigarette initiation over a three-month time course using a burst-of-measurement approach[16] and examine EMA reactivity in e-cigarette initiation. Though a recent meta-analysis of EMA studies assessing substance use (including nicotine) with people who use substances did not find a different in adherence rates with the length of assessment period,[17] completing EMAs reports for three consecutive months is likely burdensome to participants, costly to researchers, and likely to result in lower adherence over time. Understanding if this burst-of-measurement approach, with five individual weeks of assessments spread over the course of three total months, is feasible is important to understand contextual influences on e-cigarette use over longer periods of time.

Method

Participants

Participants were people who smoke and who were interested in trying out e-cigarettes. Eligibility criteria were: (a)

18+ years of age, (b) currently smoking daily for at least the last 3 months with 100+ lifetime cigarettes smoked, (c) currently not using non-cigarette tobacco (e.g., cigars, chewing tobacco, pipe), (d) currently not using any smoking cessation pharmacotherapy (though use of non-pharmacological smoking cessation aids was not exclusionary), (e) interested in trying out e-cigarettes, with no previous e-cigarette experience, (f) willing to initiate e-cigarette use during the study, (g) not pregnant, planning to become pregnant, or breast feeding, and (h) fluent in English.

Procedures

Study participation lasted 3.5 months, and consisted of five lab visits and, for participants randomized to the EMA condition, 4 weeks of EMA (see Fig. 1). At each lab visit, participants completed biochemical tests and questionnaires. All procedures were approved by the first author's affiliated institutional review board.

After phone screening, interested individuals came to the lab to provide written informed consent, and to biochemically verify smoking status. If expired breath carbon monoxide was < 6 ppm,[18,19] a dipstick urine test (NicAlert) was used to confirm smoking status. Participants were then randomized to either complete EMA or not on a 1:1 schedule with 4 participants per block using SAS PROC PLAN syntax.[20] EMA participants were given a handheld device (i.e., Hewlett Packard iPAQ 110) to complete EMA reports, and were asked to practice using the device for 1−2 days. Data collection started upon confirming by phone that participants were comfortable with the EMA reporting. EMA participants had to achieve a score of 75 % or higher on the study's EMA adherence summary score, which consisted of completing morning reports (yes/no per day; 20 % of the EMA score), evening reports (yes/no per day; 20 % of the EMA score), and audibly-prompted mini-surveys (percent of audibly prompted reports participants completed per day; 60 % of score), while not exceeding allotted time for 'sleep' (−10 % of the EMA score) or 'suspend' (−10 % of the EMA score) modes or failing to initiate at least one report of smoking or vaping (−30 % of the EMA score), unless participants reported being abstinent from either smoking or e-cigarette use. Audibly-prompted reports occurred up to six times per day, randomly occurring between 0:00−4:00, 4:00−8:00, 8:00−12:00, 12:00−16:00, 16:00−20:00, and 20:00−24:00 when the device was not in 'sleep' or 'suspend'. At the end of each week, participants data were downloaded and their adherence was calculated with an excel file. A research assistant then gave the participant feedback on the types of prompts (morning report, evening report, random prompts, cigarette reports, e-cigarette reports, sleep time, suspend time) that decreased their adherence and encouraged them to increase their adherence. Participants were required to pass the EMA adherence check at the end of their first week of the study because the EMA protocol was the independent variable in the study.

Participants returned to the lab one week later (Visit 2 − e-cigarette initiation) and received a 2nd generation e-cigarette starter kit with the flavor of their choice (i.e., Classic Tobacco, Magnificent Menthol, or Variety Pack). Female participants needed to produce a negative urine pregnancy test to receive the e-cigarette starter kit. EMA participants were asked to continue to complete EMA reporting on cigarette use and e-cigarette use for the following week.

All participants returned to the lab for 1-week, 1-month and 3-month follow-ups post e-cigarette initiation. EMA participants completed EMA reporting during the week immediately preceding lab visits. For the 1- and 3-month follow-

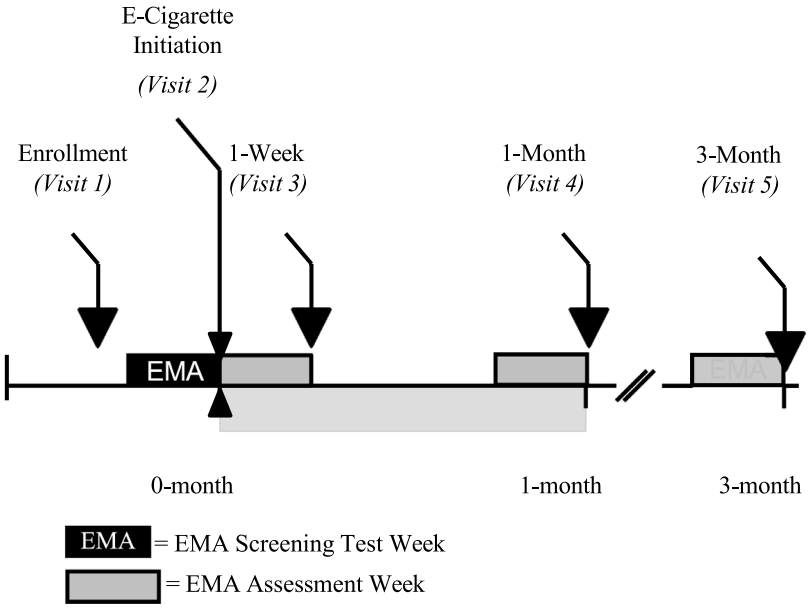

Fig. 1 Study timeline for ecological momentary assessment protocol

Notes. Timeline of study participation showing 'burst of measurement' ecological momentary assessment (EMA) approach in which EMA was delivered in distinct, 1-week epochs immediately prior to e- cigarette initiation, immediately following e-cigarette initiation, and 1 month and 3 months following e- cigarette initiation.

ups, staff called EMA participants to remind them to turn on their EMA devices.

Participants were compensated for their participation, with escalating compensation per lab visit (i.e., $10 for enrollment, $35 for 3-month), and EMA reporting (i.e., $40 for the baseline week, and $55 for the 3-month, directly proportional to EMA adherence), with a total possible compensation of $120 for non-EMA and $310 for EMA participants. Participants who decided to leave the study early were asked to complete an early termination questionnaire by phone, email, or in person.

Measures

Biochemical assessments

Expired breath carbon monoxide was assessed with a Bedfont piCO$^+$ Smokerlyzer. Cotinine was assessed via saliva samples collected with cotton dental rolls (SalivaBio OralSwabs) placed inside the cheek. Samples were frozen on site and shipped to a laboratory (Salimetrics LLC) for analysis using duplicate enzyme immune assay.

EMA items

Short, logic-branched, multiple-choice and slider-bar items were used. Audibly prompted mini-surveys (21 items) assessed current mood (6 items), other subjective states (e.g., hunger; 4 items), craving (2 items),[21] environmental (e.g., inside/outside), social (e.g., alone/with others; with children), and physiological (i.e., caffeinated or intoxicating substance) context (9 items). The same items were used in user-initiated reports of cigarette and e-cigarette consumption, which also assessed mood and other subjective states retrospectively (i.e., right now vs. right before smoking or vaping), reason for this instance of smoking / vaping (1 item), number of cigarettes smoked/ number of e-cigarette puffs taken (1 item), and, for e-cigarettes only, nicotine strength used (1 item).

Questionnaires

Questionnaires were administered via REDCap (Research Electronic Data Capture).[22] Logic-branching was used to reduce participant burden. Surveys addressed several constructs. Of relevance here are the assessment of motivation to quit smoking, as measured on a 0—10 Likert scale ranging from "Stopping smoking is not at all important to me" (0) to "stopping smoking is the most important goal in my life" (10),[23] past week e-cigarette and cigarette use, and nicotine dependence as assessed by the Fagerström Test for Nicotine Dependence (FTND).[24]

Data analytic plan

First, *t*-tests (for continuous variables) and chi-square tests (for categorical variables) examined whether there were differences between EMA and non-EMA groups at baseline with respect to demographic and smoking history variables. Then, to summarize adherence to the EMA protocol, we calculated percentages describing EMA behaviors. These analyses used data from the EMA group only, as the non-EMA group did not have EMA data. We calculated these summaries separately per EMA week, as each week represented a new burst of measurement, and thus it was of interest to see if compliance would differ across different assessment weeks. For each person, we calculated the percentage of time they met the EMA compliance criterion (e.g.,% of days they completed the morning report;% of times they responded to an alert to complete a random mini-assessment), and then averaged across participants to provide the overall summary percentage.

To examine if there were differences between randomized groups in our key variables of interest that might be impacted due to EMA reactivity, we used a descriptive approach. Our sample size was quite low, meaning a non-significant *p*-value would be uninformative. Instead, we calculated means with standard deviations, and based on these, calculated Cohen's *d* to provide insight into the magnitude of group differences. Because our sample size was low, we then also calculated 95 % confidence intervals around this effect size, as recommended,[25] using the formula provided by Hedges and Olkin.[26]

Results

Participants were predominantly male (61.0 %), White (54.3 %) or African American (38.9 %) and were an average 44.1 (SD = 12.6) years of age. The sample was socio-economically disadvantaged. Specifically, few participants were employed full-time (17.0 %) or had a college degree or more (23.7 %); most had an annual household income of under $25,000. At baseline, participants smoked 13.0 (SD = 8.4) cigarettes per day on average and reported mild to moderate nicotine dependence (M_{FTND} = 4.0; SD = 2.3). Participants randomly assigned to EMA and non-EMA groups did not significantly differ on any demographic or smoking characteristics at baseline (see Table 1).

Feasibility of EMA for studying e-cigarette use initiation

Requests for study enrollment exceeded staff capacity; we completed 20 successful enrollments per month. A subset (17 %; n = 5) of participants randomized to the EMA group failed the EMA adherence check in the first week; and an additional 10 % (n = 3) chose to discontinue the study for other reasons. The EMA protocol was therefore not feasible for approximately a third of participants randomly assigned to EMA.

For participants in the EMA group who passed the initial adherence check, EMA adherence was consistently high during the three subsequent EMA assessment bursts (Table 2), with response rates to audibly-prompted mini-surveys, and morning and evening reports exceeding 90 %. When not abstinent from smoking, participants reported at least one cigarette and/or e-cigarette use on average on 84—92 % of days. The sleep function was somewhat problematic, with participants blocking off more than the allotted 10 h of 'sleep' per day in the screening week, though adherence to

Table 1 Sample characteristics by EMA vs Non-EMA group.

	EMA (n = 30)		Non-EMA (n = 29)			
Demographics	*M* or%	*SD* or *N*	*M* or%	*SD* or *N*	t / χ^2	p-value
Age	46.6	(10.9)	41.5	(13.8)	1.55	0.13
Sex (% female)	43.3	(13)	34.5	(10)	0.60	0.49
Ethnicity (% Hispanic)	3.3	(1)	3.5	(1)	0.00	0.98
Race					0.50	0.64
White	50.0	(15)	58.6	(17)		
African American	43.3	(13)	34.5	(10)		
Other	6.7	(2)	6.9	(2)		
Education					1.08	0.58
High school or less	30.0	(9)	41.4	(12)		
Some college	46.7	(14)	34.5	(10)		
College degree or more	23.3	(7)	24.1	(7)		
Employment					2.14	0.55
Full-time	16.7	(5)	17.2	(5)		
Part-time	20.0	(6)	27.6	(8)		
Disabled	30.0	(9)	37.9	(11)		
Other (unemployed, retired)	33.3	(10)	17.2	(5)		
Annual Household Income					1.64	0.44
Less than $25,000	73.3	(22)	67.9	(20)		
$25,000 - $49,999	13.3	(4)	25.0	(7)		
$50,000 or more	13.3	(4)	7.1	(2)		
Smoking Descriptors						
Cigarettes per day	12.9	(9.5)	14.6	(10.0)	−0.67	0.51
FTND†	3.7	(2.2)	4.2	(2.4)	−0.84	0.42
Age at first cigarette	14.6	(3.3)	16.0	(7.2)	−0.96	0.34
Years smoking	26.6	(11.3)	17.6	(12.8)	2.87	0.006
Primary Outcome Variables						
Exposure to Smoke (CO in ppm)	28.3	(17.8)	23.5	(12.1)	1.22	0.23
Exposure to Nicotine (cotinine in ng/ml)	498.8	(380.2)	425.7	(296.0)	0.82	0.42
Motivation to Quit Smoking (0−10)	8.1	(2.4)	7.9	(2.2)	0.34	0.73

Notes. FTND= Fagerstrom Test for Nicotine Dependence; † assessed at e-cigarette initiation visit rather than enrollment visit; ppm= parts per million; ng/ml= nanograms per milliliter; all p>.05.

the 10 h of sleep expectation improved each week as participants received feedback and decreased compensation for putting their device in sleep mode for more than 10 h. The suspend function was used as intended. Retention (Fig. 2) for this burst-of-measurement EMA study was acceptable for the EMA group that passed the adherence check at Week 1 (82 %, 77 %, and 68 % for 1-week, 1-month and 3-month follow-up), but not for the non-EMA group (75 %, 64 %, and 53 % for 1-week, 1-month and 3-month follow-up). Exit interviews indicated that compensation was not sufficient to offset time required to come in for office visits, which was particularly true for non-EMA participants.

EMA reactivity

Comparisons in cigarette and e-cigarette outcomes between the EMA and non-EMA groups were not suggestive of EMA reactivity (Table 3). No consistent trend emerged in comparing the EMA vs non-EMA groups, either on variables relevant to the public health impact of e-cigarette initiation (i.e., cigarettes per day, exposure to smoke, exposure to nicotine, motivation to quit smoking), or in terms of the newly forming behavior, e-cigarette use (as measured in number of bouts of e-cigarette use per day and puffs per bout of e-cigarette use). Due to the limited sample size of this study, confidence intervals around group difference estimates (i.e., Cohen's d) were large, but means across time periods suggest that systematic group differences were either small or negligible.

The biggest group difference was small in size (Cohen's d = 0.29, CI = 0.01 − 0.59) and was in exposure to nicotine measured via salivary cotinine assessed during Visit 2, after 1 week of EMA reporting, but immediately prior to e-cigarette initiation. Specifically, EMA participants showed higher salivary cotinine (M = 499.2, SD = 315.2) than non-EMA participants (M = 334.3, SD = 240.1) at Visit 2. In Visit 3, one week later, the pattern was reversed with non-EMA participants (M = 429.3, SD = 412.3) showed higher salivary cotinine than EMA participants (M = 332.2, SD = 210.7; Cohen's d = −0.15, CI = −0.46 − 0.22). EMA and non-EMA groups did not significantly differ in salivary cotinine at Visit 4, one month after e-cigarette initiation, (Cohen's d = −0.02, CI = −0.35 − 0.38) or at Visit 5, three months after e-cigarette initiation (Cohen's d = 0.05, CI = −0.31 − 0.41).

Table 2 EMA adherence rates for persons who failed the screening test and those who completed the screening test across assessment periods.

	EMA Non-compliers $n = 5$ Screening Week	EMA Participants $n = 22$ Screening Week	EMA Participants $n = 18$ Week 1	EMA Participants $n = 17$ Month 1	EMA Participants $n = 15$ Month 3
EMA Report Compliance (%)					
Morning report completion	66.4	96.1	94.0	93.8	93.8
Evening report completion	59.7	96.1	94.0	93.6	91.4
Random report completion	54.4	92.7	93.1	92.6	91.6
Cigarette or e-cigarette use reporting	72.0	91.8	92.5	84.0	89.6
Exceeded Sleep and Suspend Time Limits (average number of days during each 7-day EMA period)					
>10 hrs sleep	5.5	2.0	0.9	1.0	1.3
> 4 hrs suspend	0.0	0.1	0.0	0.1	0.1

Notes. EMA= Ecological momentary assessment.

The only other difference that was small in size (rather than negligible) was motivation to quit smoking, which was higher in the EMA group ($M = 8.6$, $SD = 1.7$) relative to the no-EMA group ($M = 7.7$, $SD = 2.4$) at Visit 5 (Month 3) only and was not statistically different (Cohen's d CI = −0.17 — 0.64).

Discussion

Our findings suggest that EMA reactivity within the context of e-cigarette initiation is either small or negligible. The largest group difference we observed was on salivary cotinine assessed during Visit 2, after 1 week of EMA reporting, but before e-cigarette initiation, where EMA participants had higher cotinine than non-EMA participants. Subsequently, however, the directionality reversed, with non-EMA participants having higher cotinine values. The inconsistency of these group differences suggests random fluctuations around largely similar means. Given the limited sample size of our study, we cannot, of course, rule out the existence of small effects. Our results do suggest, however, that medium to large effects due to engaging in EMA are unlikely to occur on variables relevant to measuring the public health impact of e-cigarette initiation, or on variables summarizing e-cigarette use. This constellation of findings is concordant with previous research that utilized EMA to study substance use,[7,9,27] and implies that the act of engaging in EMA does not contaminate the behaviors under assessment in the context of e-cigarette initiation.

Results of our pilot study also support the feasibility of using an EMA burst-of-measurement approach to capture e-cigarette initiation, with some caveats. First, there was a subset of participants — almost a third of participants who were randomized to complete EMA — who did not complete the EMA protocol, either because they were withdrawn by the study staff for having low adherence during the screening week (17%) or the participants electively withdrew (10%). The screening and consent process may need to be even more explicit and include examples of what EMA prompts sound like and how often they may occur. More work is needed to understand the reasons for low adherence among this subset of participants. For the group who remained in the study, generally, response rates to EMA mini-surveys were consistently high across EMA periods, suggesting that participants are unlikely to succumb to assessment fatigue when needing to participate in multiple EMA periods. Retention rates were also acceptably high in the EMA group, though notably not in the no-EMA group, who received less compensation. There was compensation escalation at each visit; however, the $10 for enrollment was deemed unacceptably low and $35 for Month 3 was not escalated enough to achieve desired retention in the non-EMA group. To maximize retention rates, our results indicate that compensation rates needs to be higher or could be offered entirely remotely to offset travel costs and time. We further recommend against the use of user-initiated sleep and suspend functions, as these features appeared to complicate rather than enhance the end-user experience.

Study limitations include the limited sample size, and a largely low socioeconomic status sample of adults recruited in an urban academic medical center. This sample, therefore, may not represent the breadth of e-cigarette users. This study also used iPAQs given the low socioeconomic status of participants, which may have resulted in lower adherence than app-based EMA monitoring. Results presented here may not be an accurate reflection of future EMA adherence rates with app-based monitoring on personal cell phones or study cell phones. In addition, though e-cigarette use was self-reported for both EMA and non-EMA participants, these may be underestimates, and could be enhanced with blue-tooth enabled e-cigarettes to more accurately measure bouts.[28] Finally, there was a significant difference in smoking experience between randomized groups (i.e., longer smoking careers in those assigned to the EMA group), but given a lack of significant difference in age and other smoking characteristics, it is unclear if this difference could have meaningfully impacted results.

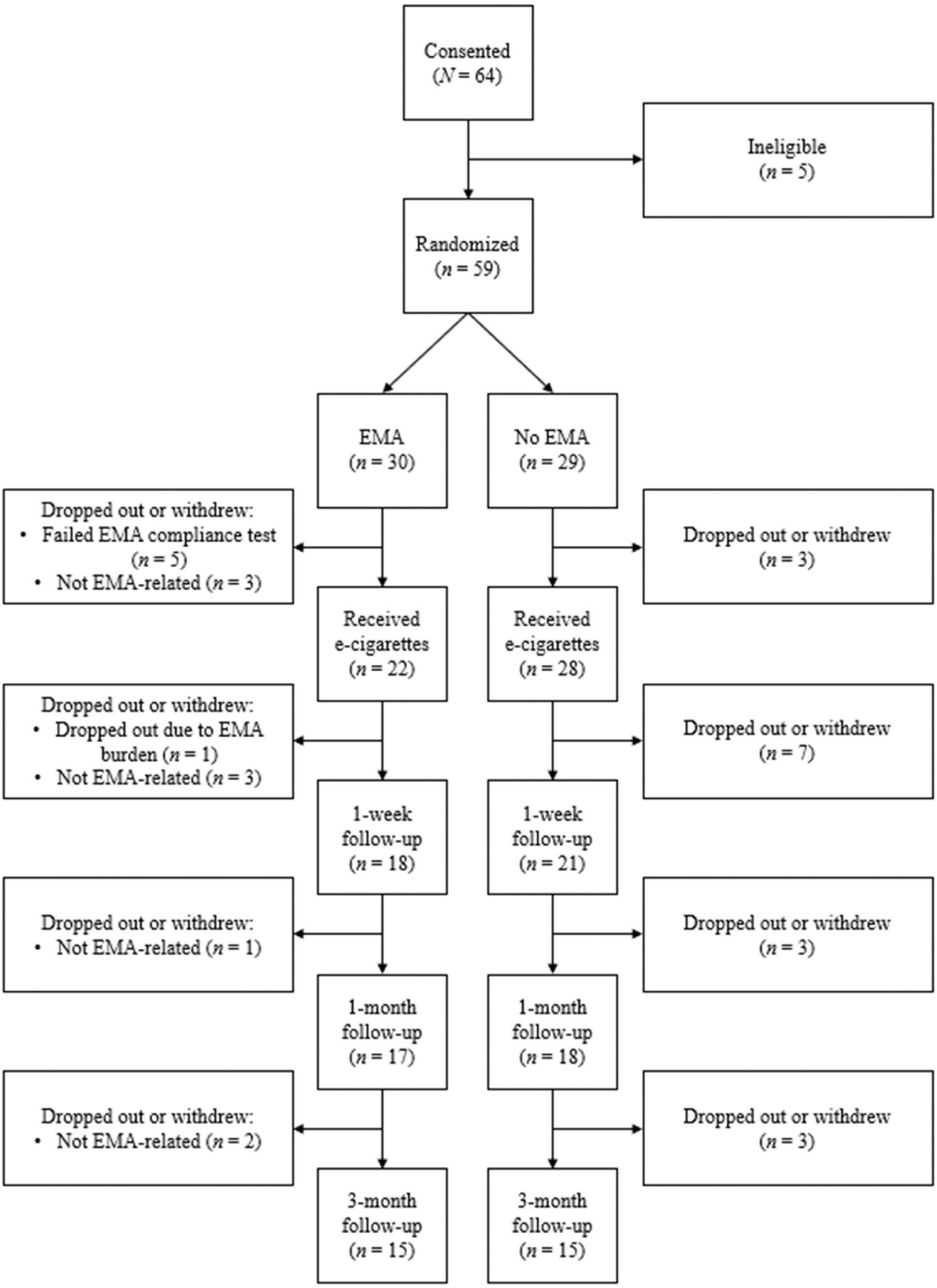

Fig. 2 Consort diagram showing participant enrollment and attrition for ecological momentary assessment group, and no ecological momentary assessment group.

Table 3 Cigarette and e-cigarette smoking outcomes for EMA vs non-EMA groups.

	EMA (n = 30) Mean (SD)	No EMA (n = 29) Mean (SD)	*Cohen's d*	*Cohen's d* CI (95 %)	
				Lower	*Upper*
Number of cigarettes smoked (per day)				Average d = 0.06	
E-cig initiation	11.3 (11.0)	12.4 (7.6)	−0.06	−0.34	0.22
1-week	8.8 (6.9)	6.7 (6.1)	0.17	−0.17	0.50
1-month	8.1 (6.2)	6.5 (6.4)	0.13	−0.22	0.47
3-month	7.7 (5.7)	7.6 (8.6)	0.01	−0.35	0.37
Exposure to smoke (expired breath CO, in ppm)				Average d = 0.02	
E-cig initiation	26.2 (12.7)	23.8 (12.2)	0.09	−0.19	0.38
1-week	25.5 (14.8)	25.2 (18.0)	0.08	−0.32	0.34
1-month	25.4 (14.5)	22.9 (19.3)	0.07	−0.28	0.42
3-month	23.1 (11.9)	28.9 (22.0)	−0.16	−0.53	0.20
Exposure to nicotine (salivary cotinine, in ng/ml)				Average d = 0.04	
E-cig initiation	499.2 (315.2)	334.3 (240.1)	0.29	0.01	0.59
1-week	332.2 (210.7)	429.3 (412.3)	−0.15	−0.48	0.19
1-month	285.3 (213.7)	301.0 (336.6)	−0.02	−0.37	0.31
3-month	279.7 (175.6)	257.9 (256.4)	0.05	−0.31	0.41
Motivation to quit smoking (single-item measure, 0—10 scale)				Average d = 0.03	
E-cig initiation	7.9 (2.5)	7.9 (2.2)	0.00	−0.28	0.29
1-week	7.8 (1.8)	8.3 (2.0)	−0.12	−0.46	0.22
1-month	8.0 (2.3)	7.9 (2.1)	0.02	−0.35	0.38
3-month	8.6 (1.7)	7.7 (2.4)	0.23	−0.17	0.64
Bouts e-cigarette use per day				Average d = 0.04	
1-Week	6.1 (8.0)	5.6 (7.1)	0.04	−0.29	0.36
1-Month	7.6 (20.7)	9.5 (23.2)	−0.05	−0.38	0.29
3-month	4.7 (10.8)	2.5 (5.2)	0.13	−0.23	0.50
Number of puffs per bout e-cigarette use				Average d = 0.06	
1-Week	17.4 (22.4)	12.6 (10.9)	0.13	−0.20	0.46
1-Month	12.9 (20.2)	16.7 (21.1)	−0.09	−0.42	0.25
3-month	15.9 (28.9)	8.4 (25.5)	0.14	−0.23	0.50

Notes. EMA = ecological momentary assessment. CI = Confidence Interval. Standard deviations in parentheses; CO = carbon monoxide, ppm= parts per million; ng/ml= nanograms per milliliter; * p<.05.

Conclusions

Results of this study have some preliminary clinical implications. Though not currently approved as medical devices in the United States[29] or any other country to the authors knowledge, the United Kingdom has provided guidance for how e-cigarettes and other nicotine delivery systems could apply for consideration as medical devices.[30] In addition, a recent review has shown using e-cigarettes with nicotine results in higher quit rates than NRT or non-nicotine e-cigarettes[31] and persons may prefer e-cigarettes given their similarity in inhalation to traditional cigarettes, as well as their customizations for nicotine level and flavor.[32] Results of this study suggest that asking repeated questions about cigarette use, e-cigarette use, and their context will not necessarily increase either behavior or exposure to nicotine levels — meaning that providers who are asking their patients to monitor their e-cigarette use during an attempt to quit traditional cigarettes is unlikely to worsen smoking or quit outcomes. Simply monitoring traditional smoking and e-cigarette use may not change either behavior, and so enhancing motivation quit outcomes with behavioral therapies[33] may be needed for persons wishing to replace traditional cigarettes with e-cigarettes. Though motivation to quit smoking was higher in the EMA group three months after e-cigarette initiation, this effect was small and would need to be replicated in additional studies to encourage providers to assign smoking and e-cigarette monitoring in order to increase future motivation to quit smoking.

Results from the present investigation support the feasibility of EMA for the study of e-cigarette initiation and use, within the subset of participants who passed the EMA adherence test within the first week — that is, they completed at

Note. Of the n = 5 who were excluded between consent and randomization, one was excluded at baseline because we were unable to confirm their status as a current daily smoker at baseline (i.e., their CO reading was 4 ppm). The remaining four consented but were not randomized, as the choice to randomize participants to complete EMA versus not complete EMA was not reflected in the original study protocol (the purpose of the study was to examine the feasibility of using EMA to characterize e-cigarette initiation among adults who smoke daily in one arm only). An IRB amendment approving randomization was approved after these four participants had consented to participate. Thus, they completed the study but are not reflected here because they did not agree to be randomized.

least 75 % of the EMA protocol in their first week. This suggests that the participants who are adherent to the EMA protocol do not become over-burdened or have other negative reactions to the EMA protocol. For this study, the independent variable was EMA reporting, and so participants were only included if they could complete the EMA reporting. However, for future EMA studies recruiting people who smoke daily initiating e-cigarette use, more incentives, additional training on the EMA reporting protocol particularly around user-initiated sleep mode, or additional information at screening or consent on the burden of EMA procedures may be needed, in order to prevent recruiting participants who are not able to complete the EMA protocol. Traditional concerns associated with the EMA methodology such as participant reactivity, did not appear to be active in people who smoke who are initiating e-cigarette use. In addition, this study tested a novel burst-of-measurement approach, which proved to be effective for capturing behavior under investigation across a several brief (7 day) time-periods over the course of three months, without dramatically increasing participant burden.

Conflicts of interest

None.

Ethical considerations

The human subjects research described was carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) and Uniform Requirements for manuscripts submitted to Biomedical journals. Informed consent was obtained for all participants prior to their participation in any study-related activities. This research was approved by the Massachusetts General Hospital institutional review board.

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References

1. Food and Drug Administration. Deeming tobacco products to be subject to the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the sale and distribution of tobacco products and required warning statements for tobacco products. Final rule. Food and Drug Administration;2016. 0097−6326.
2. U.S. Department of Health and Human Servivces. E-cigarette Use Among Youth and Young Adults. Atlanta, GA: U.S. Department of Health and Human Servivces, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2016.
3. World Health Organisation. Electronic Nicotine Delivery Systems. World Health Organisation; 2014.
4. Ali FRM, Seaman EL, Crane E, Schillo B, King BA. Trends in US e-cigarette sales and prices by nicotine strength, overall and by product and flavor type, 2017-2022. Nicotine Tob Res. 2023;25 (5):1052−6. https://doi.org/10.1093/ntr/ntac284.
5. Stone AA, Shiffman S. Ecological momentary assessment (EMA) in behavorial medicine. Ann Behav Med. 1994;16(3):199−202.
6. Shiffman S. Commentary on McCarthy et al. (2015): ecological momentary assessment−reactivity? Intervention? Addiction. 2015;110(10):1561−2. https://doi.org/10.1111/add.13050.
7. Hufford MR, Shields AL, Shiffman S, Paty JA, Balabanis M. Reactivity to ecological momentary assessment: an example using undergraduate problem drinkers. Psychol Addict Behav. 2002;16(3):205−11. https://doi.org/10.1037/0893-164X.16.3.205.
8. McCarthy DE, Minami H, Yeh VM, Bold KW. An experimental investigation of reactivity to ecological momentary assessment frequency among adults trying to quit smoking. Addiction. 2015;110(10):1549−60. https://doi.org/10.1111/add.12996.
9. Rowan PJ, Cofta-Woerpel L, Mazas CA, Vidrine JI, Reitzel LR, Cinciripini PM, et al. Evaluating reactivity to ecological momentary assessment during smoking cessation. Exp Clin Psychopharmacol. 2007;15(4):382−9. https://doi.org/10.1037/1064-1297.15.4.382.
10. McCarthy DE, Piasecki TM, Fiore MC, Baker TB. Life before and after quitting smoking: an electronic diary study. J Abnorm Psychol. 2006;115(3):454−66. https://doi.org/10.1037/0021-843X.115.3.454.
11. Huh J, Leventhal AM. Intraindividual covariation between e-cigarette and combustible cigarette use in Korean American emerging adults. Psychol Addict Behav. 2016;30(2):246−51. https://doi.org/10.1037/adb0000141.
12. Camenga DR, Haeny AM, Krishnan-Sarin S, O'Malley SS, Bold KW. Pilot ecological momentary assessment study of subjective and contextual factors surrounding e-cigarette and combustible tobacco product use among young adults. Int J Environ Res Public Health. 2021;18(21):11005. https://doi.org/10.3390/ijerph182111005.
13. Piper ME, Baker TB, Zwaga D, Bolt DM, Kobinsky KH, Jorenby DE. Understanding contexts of smoking and vaping among dual users: analysis of ecological momentary assessment data. Addiction. 2022;117(5):1416−26. https://doi.org/10.1111/add.15747.
14. Shiffman S. Ecological momentary assessment (EMA) in studies of substance use. Psychol Assess. 2009;21(4):486−97. https://doi.org/10.1037/a0017074.
15. Ferguson SG, Shiffman S. Using the methods of ecological momentary assessment in substance dependence research −smoking cessation as a case study. Subst Use Misuse. 2011;46 (1):87−95. https://doi.org/10.3109/10826084.2011.521399.
16. Sliwinski MJ. Measurement-burst designs for social health research. Soc Person Psychol Compass. 2008;2(1):245−61. https://doi.org/10.1111/j.1751-9004.2007.00043.x.
17. Jones A, Remmerswaal D, Verveer I, Robinson E, Franken IHA, Wen CKF, et al. Compliance with ecological momentary assessment protocols in substance users: a meta-analysis. Addiction. 2019;114(4):609−19. https://doi.org/10.1111/add.14503.

18. Benowitz NL, Bernert JT, Foulds J, Hecht SS, Jacob P, Jarvis MJ, et al. Biochemical verification of tobacco use and abstinence: 2019 update. Nicotine Tob Res. 2020;22(7):1086–97. https://doi.org/10.1093/ntr/ntz132.
19. Cummings SR, Richard RJ. Optimum cutoff points for biochemical validation of smoking status. Am J Public Health. 1988;78(5):574–5.
20. Deng C., Graz J. Generating randomization schedules using SAS programming. SUGI-27, Paper 267-27. Research Triangle Park, North Carolina, https://support.sas.com/resources/papers/proceedings/proceedings/sugi27/p267-27.pdf
21. West R, Ussher M. Is the ten-item Questionnaire of Smoking Urges (QSU-brief) more sensitive to abstinence than shorter craving measures? Psychopharmacology. 2010;208(3):427–32. https://doi.org/10.1007/s00213-009-1742-x.
22. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap) - a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform. 2009;42(2):377–81. https://doi.org/10.1016/j.jbi.2008.08.010.
23. Boudreaux ED, Sullivan A, Abar B, Bernstein SL, Ginde AA, Camargo Jr. CA. Motivation rulers for smoking cessation: a prospective observational examination of construct and predictive validity. Addict Sci Clin Pract. 2012;7(8). https://doi.org/10.1186/1940-0640-7-8.
24. Heatherton TF, Kozlowski LT, Frecker RC, Fagerström K. The Fagerström test for nicotine dependence: a revision of the Fagerstrom Tolerance Questionnaire. Br J Addict. 1991;86(9):1119–27. https://doi.org/10.1111/j.1360-0443.1991.tb01879.x.
25. Lee DK. Alternatives to p value: the confidence interval and effect size. Korean J Anesthesiol. 2016;69(6):555–62. https://doi.org/10.4097/kjae.2016.69.6.555.
26. Hedges LV, Olkin I. Statistical Methods for Meta-Analysis. Academic Press; 2014.
27. Litt MD, Cooney NL, Morse P. Ecological momentary assessment (EMA) with treated alcoholics: methodological problems and potential solutions. Health Psychol. 1998;17(1):48–52. https://doi.org/10.1037/0278-6133.17.1.48.
28. Pearson JL, Elmasry H, Das B, Smiley SL, Rubin LF, DeAtley T, et al. Comparison of ecological momentary assessment versus direct measurement of e-cigarette use with a bluetooth-enabled e-cigarette: a pilot study. JMIR Res Protoc. 2017;6(5):e84. https://doi.org/10.2196/resprot.6501. Published 2017 May 29.
29. U.S. Food and Drug Administration. E-cigarettes, vapes, and other electronic nicotine delivery systems (ENDS). 2022 June 29. https://www.fda.gov/tobacco-products/products-ingredients-components/e-cigarettes-vapes-and-other-electronic-nicotine-delivery-systems-ends
30. United Kingdom Medicine and Healthcare Products Regulatory Agency. Guidance for licensing electronic cigarettes and other inhaled nicotine-containing products as medicines.2022November 3. https://www.gov.uk/guidance/licensing-procedure-for-electronic-cigarettes-as-medicines
31. Hartmann-Boyce J, Lindson N, Butler AR, McRobbie H, Bullen C, Begh R, et al. Electronic cigarettes for smoking cessation. Cochrane Database Syst Rev. 2022;11(11):CD010216. https://doi.org/10.1002/14651858.CD010216.pub7.
32. Farsalinos K, Romagna G, Tsiapras D, Kyrzopoulos S, Voudris V. Characteristics, perceived side effects and benefits of electronic cigarette use: a worldwide survey of more than 19,000 consumers. Int J Environ Res Public Health. 2014;11:4356–73. https://doi.org/10.3390/ijerph110404356.
33. Hartmann-Boyce J, Livingstone-Banks J, Ordóñez-Mena JM, Fanshawe TR, Lindson N, Freeman SC, et al. Behavioural interventions for smoking cessation: an overview and network meta-analysis. Cochrane Database Syst Rev. 2021;1:CD013229. https://doi.org/10.1002/14651858.CD013229.pub2.