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Global Forum **on Nicotine**

Evidence, Accountability, Transparency

E-Cigarettes: current evidence and future areas of exploration

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Vaping: Current and Emerging Views

Negative Aspects

The Past



Positive Aspects

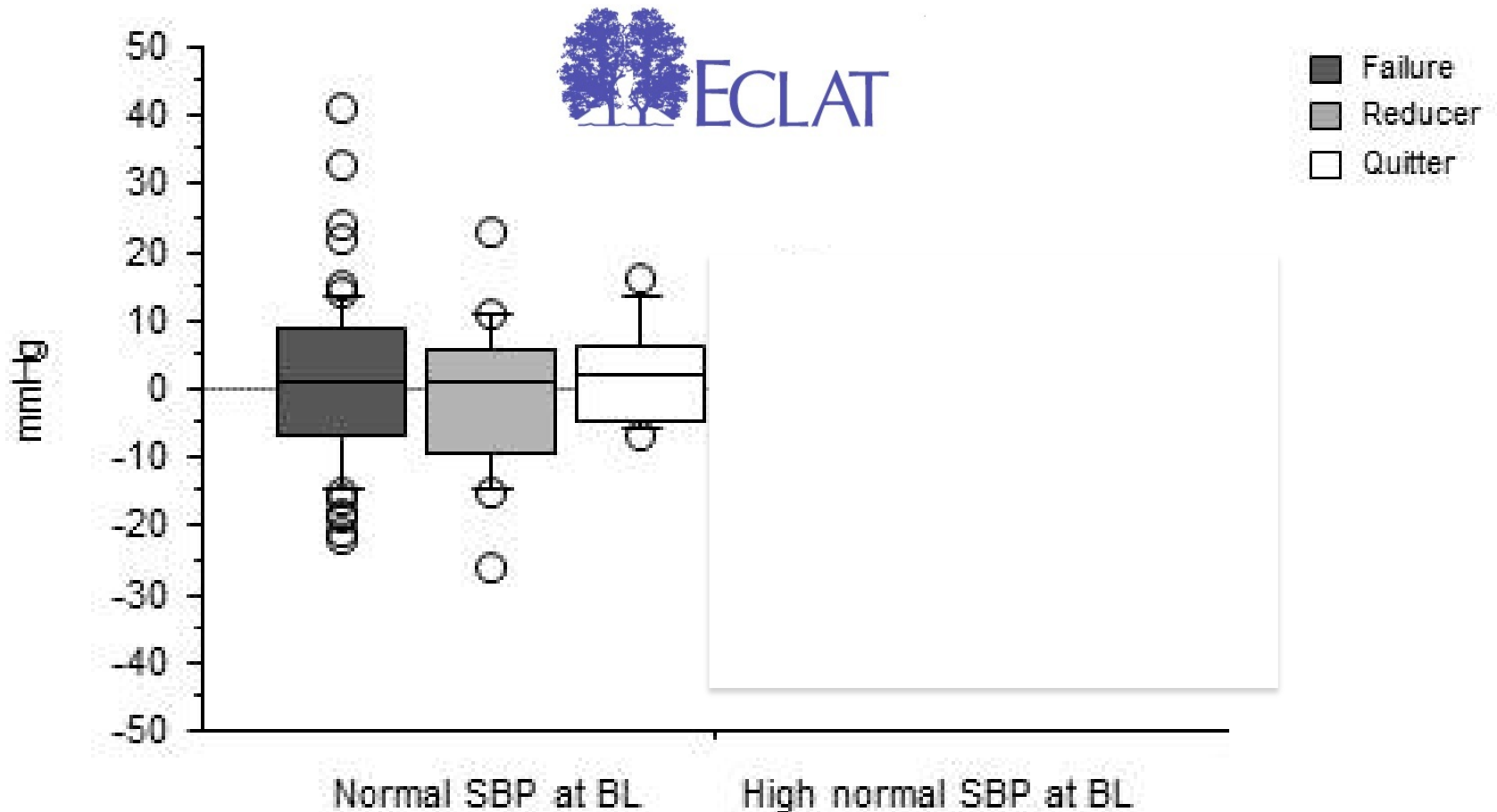
The Future

Janus head. Terracotta sculpture, from Vulci, II century BC (Rome, National Etruscan Museum of Villa Giulia).



Long-term effect of reduced smoking on BP in smokers switching to ECs

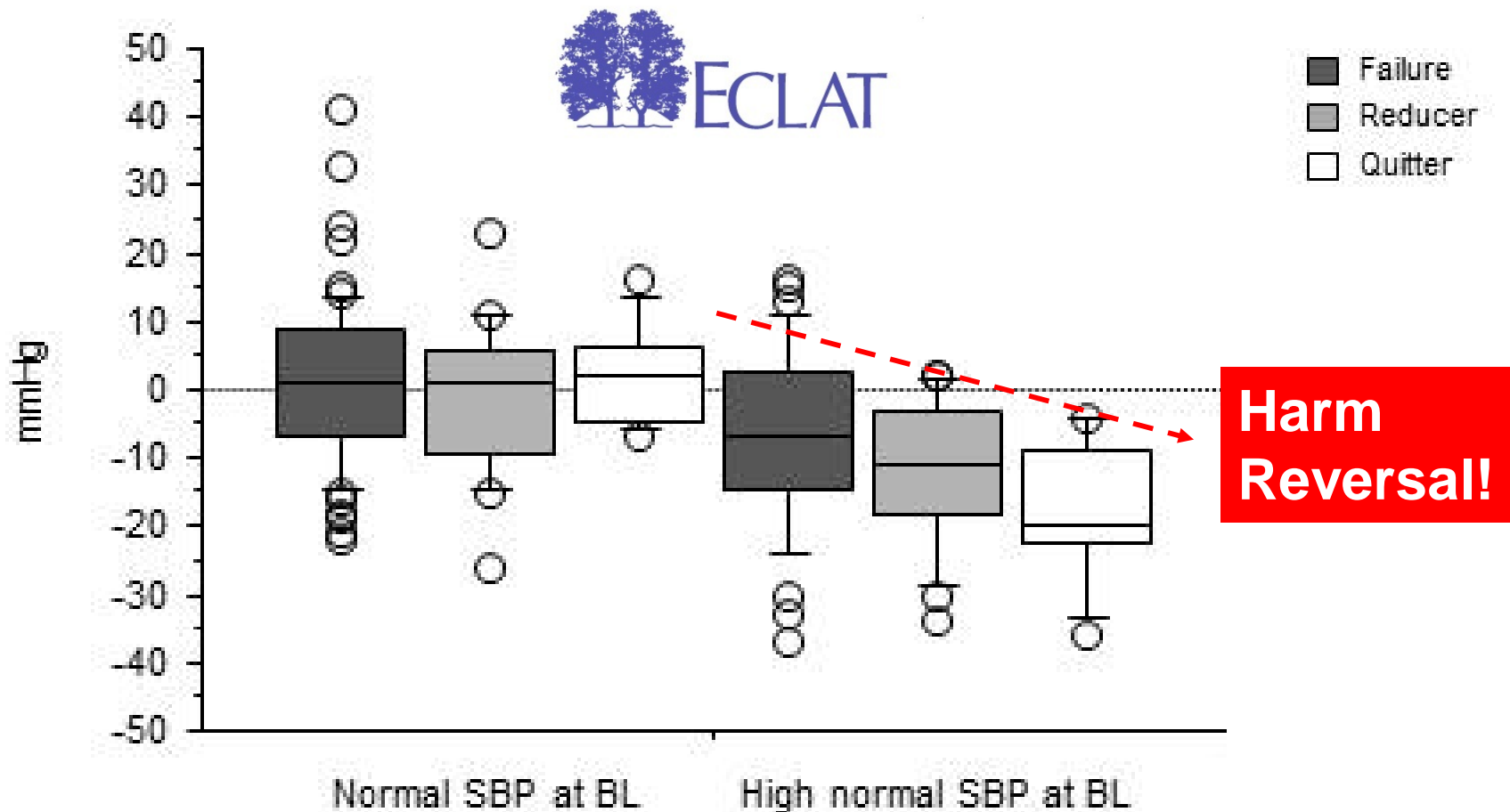
Systolic BP changes at Week 52 from baseline





Long-term effect of reduced smoking on BP in smokers switching to ECs

Systolic BP changes at Week 52 from baseline



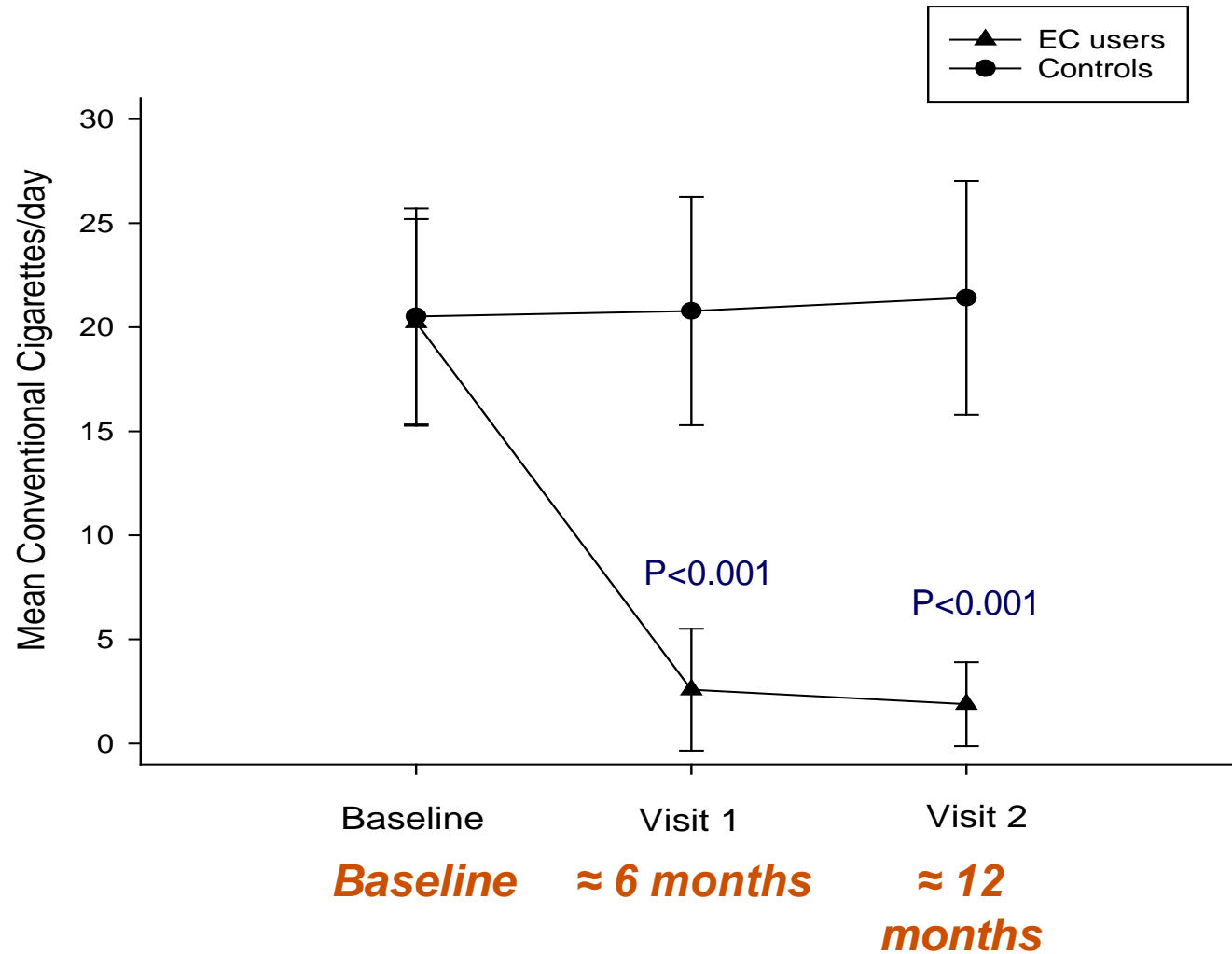
BLOOD PRESSURE CONTROL IN SMOKERS WITH ARTERIAL HYPERTENSION WHO SWITCH TO ELECTRONIC CIGARETTES

Polosa et al. (paper under review)

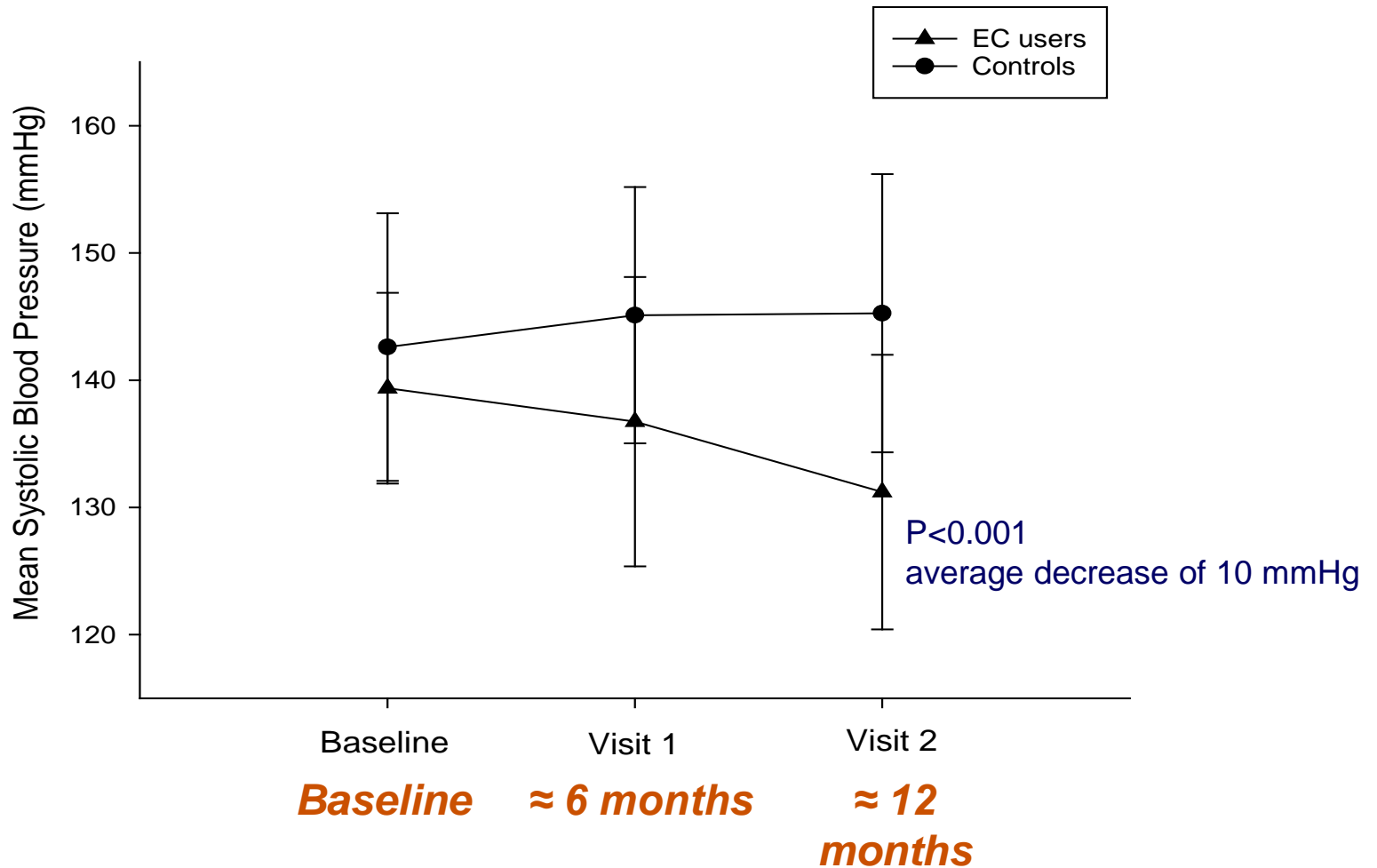


- ECs are effective and safe in RCTs of “healthy” smokers
- Smoking abstinence by using ECs may lower elevated systolic BP
- No data about EC use in smokers with pre-existing disease
- We investigated changes in BP and BP control in smoking hypertensive patients who switched to EC

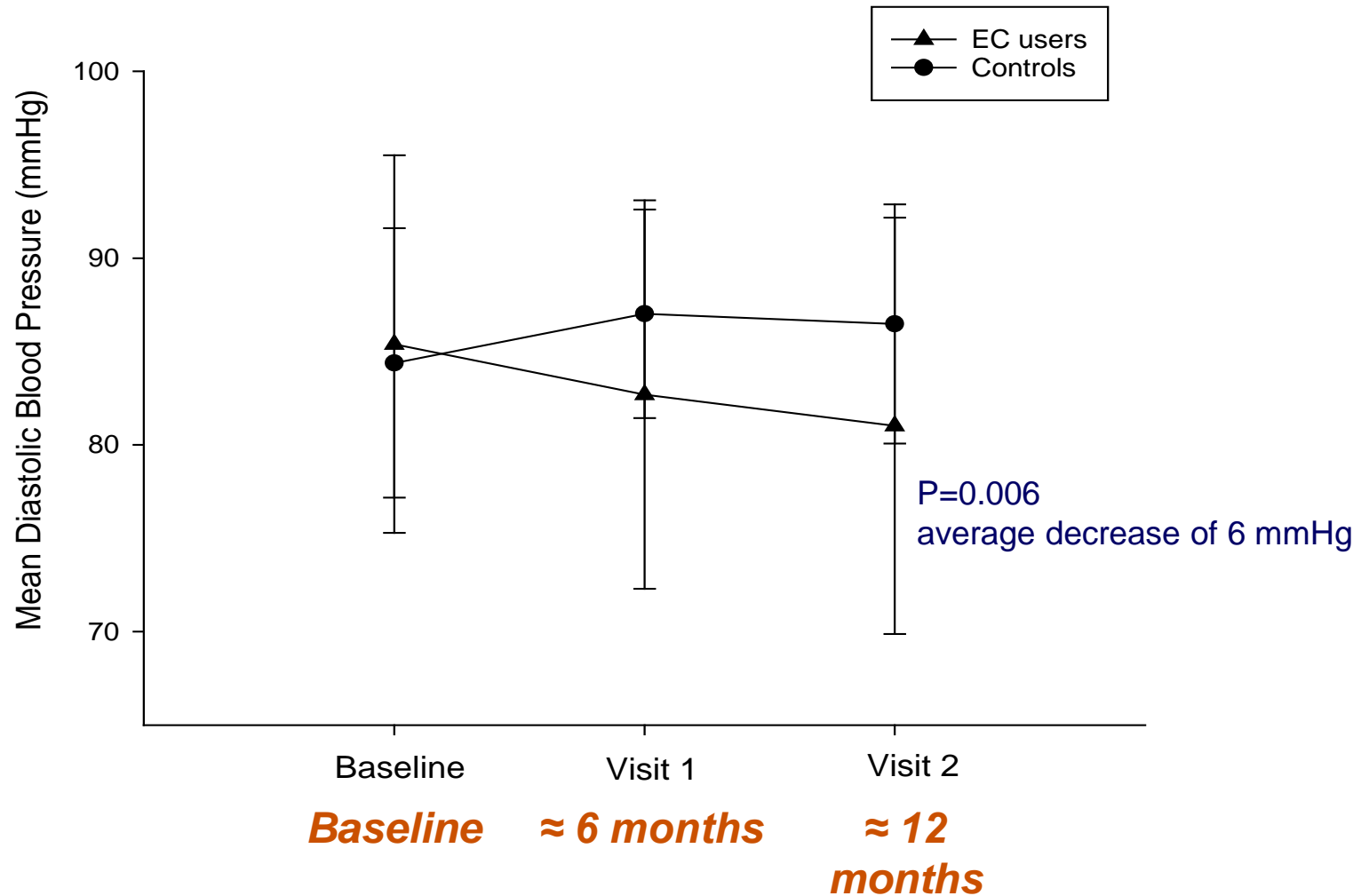
Changes in daily smoking from baseline



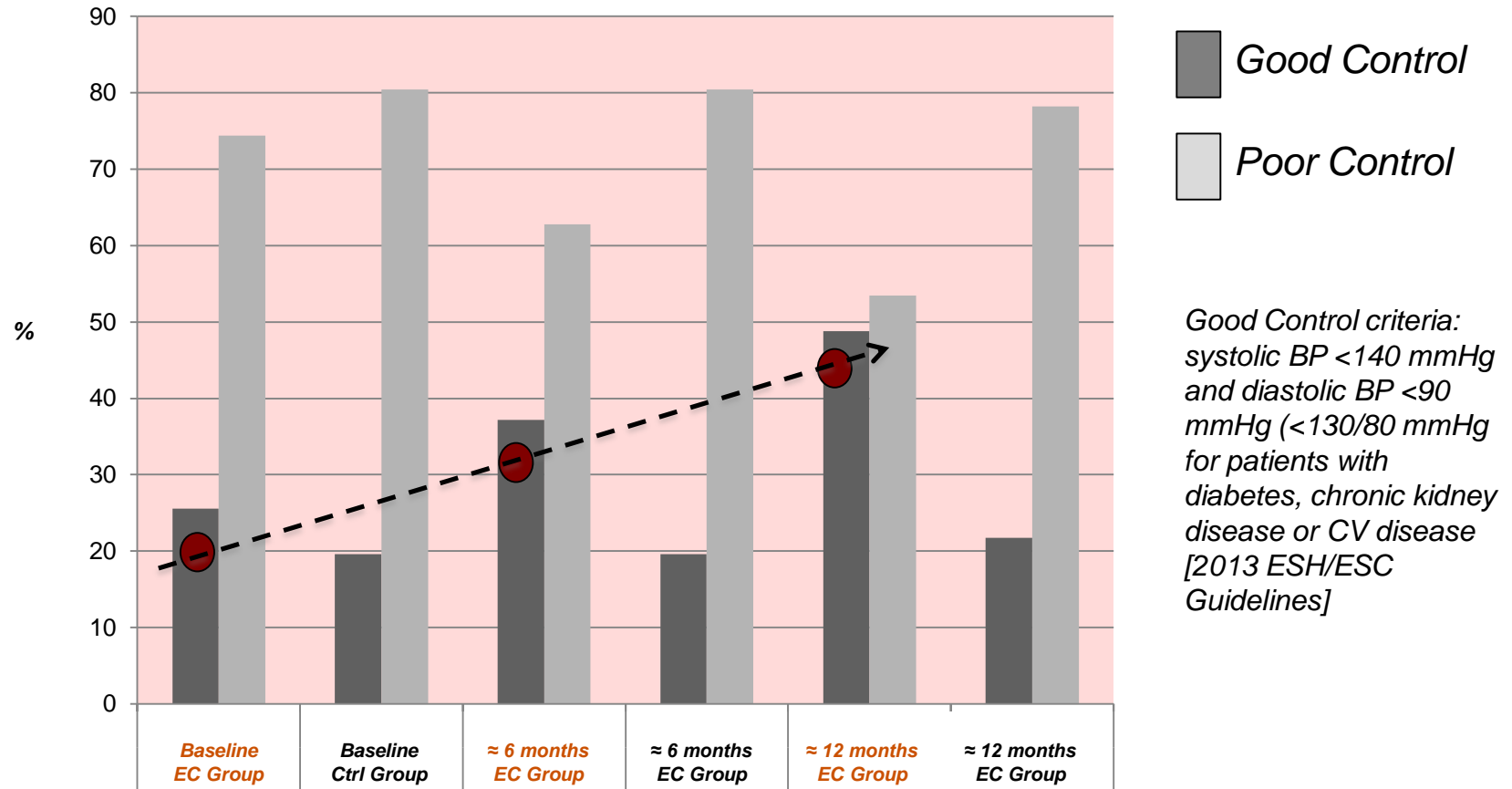
Changes in SBP from baseline



Changes in DBP from baseline



Proportion of good and poor BP control throughout the study



BLOOD PRESSURE CONTROL IN E-CIG USERS

K. Farsalinos et al. Int. J. Environ. Res. Public Health 2014

| Side effects/accidents | Total (n = 19,353) | Current smokers (n = 3682) | Former smokers (n = 15,671) | Statistic | p value |
|-------------------------|-----------------------|----------------------------------|-----------------------------------|-----------------|---------|
| | | Dual users | Single users | | |
| Hypertension (N = 2162) | | | | | |
| Worse | 19 (0.8) | 6 (1.5) | 13 (0.7) | | |
| Stable | 944 (39.9) | 194 (49.7) | 750 (38.0) | $\chi^2 = 33.8$ | <0.001 |
| Improved | 1149 (49.9) | 139 (35.6) | 1040 (52.7) | | |

Take Home Message

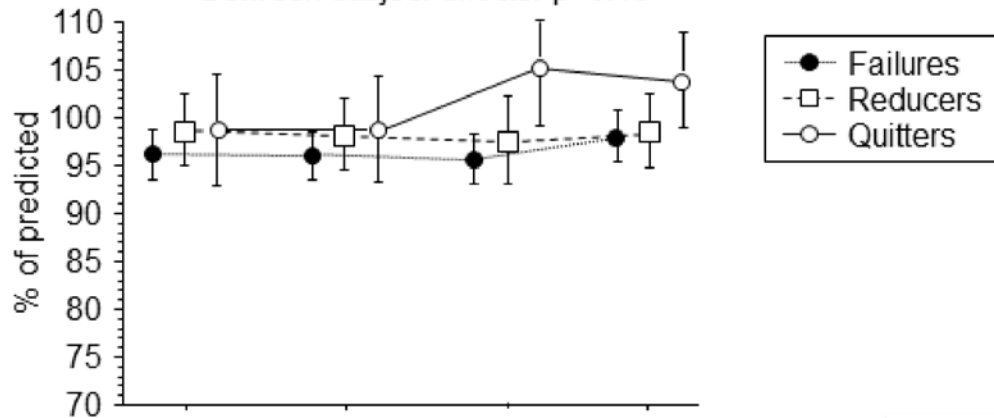
- Lowered BP and improved BP control in hypertensive patients;
- Improvements also reported in dual users;
- An helpful alternative to cigarettes, even in smokers with hypertension.

Chronic effect of abstinence/reduction on spirometry in smokers switching to ECs



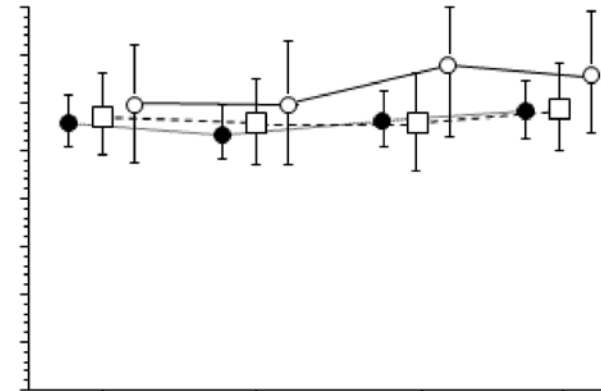
FEV₁

Between subject effects: $p=0.15$



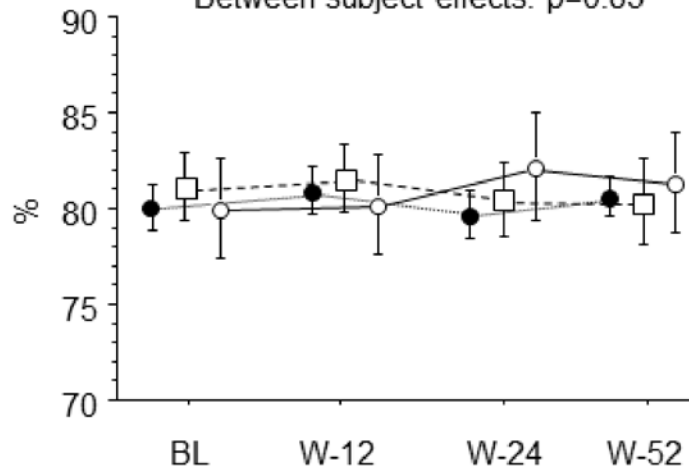
FVC

Between subject effects: $p=0.47$



FEV₁/FVC

Between subject effects: $p=0.83$

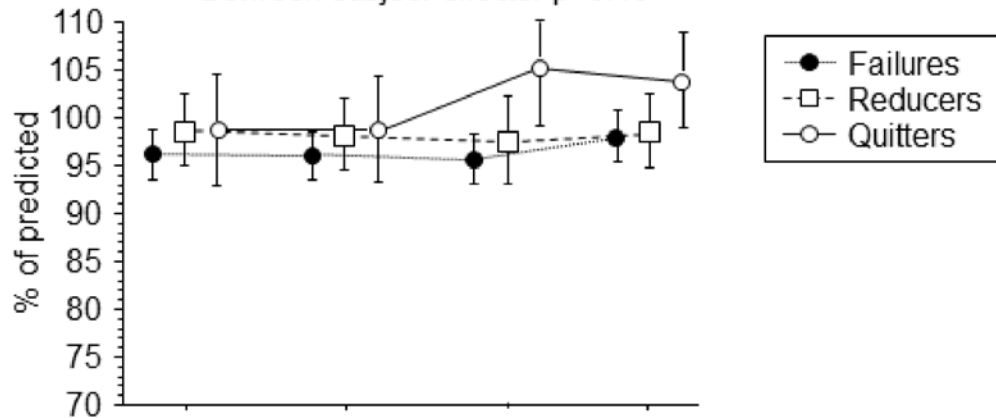


Chronic effect of abstinence/reduction on spirometry in smokers switching to ECs



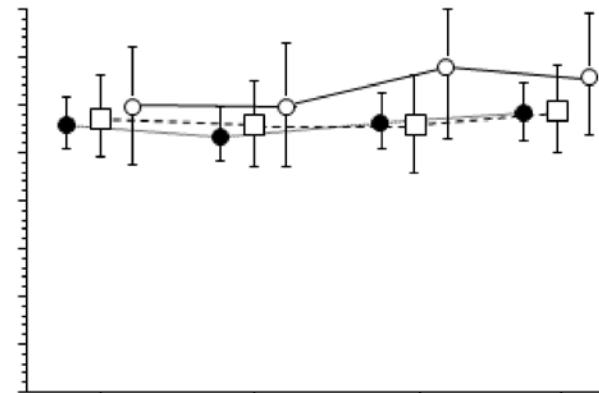
FEV₁

Between subject effects: $p=0.15$



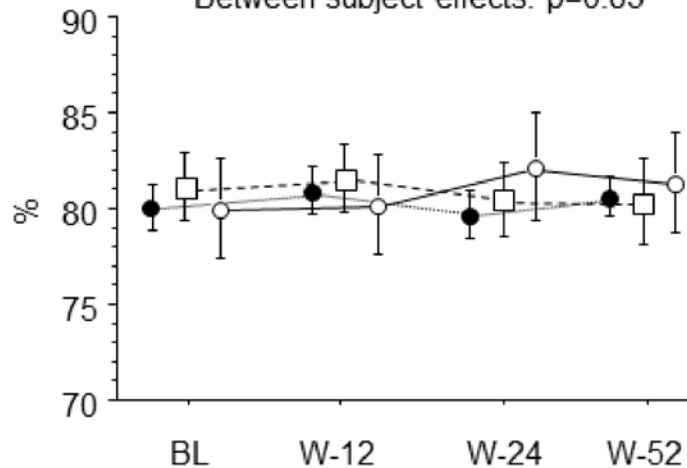
FVC

Between subject effects: $p=0.47$



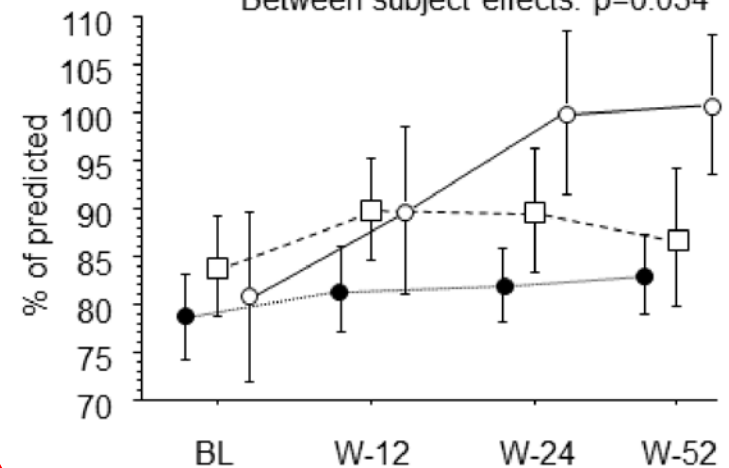
FEV₁/FVC

Between subject effects: $p=0.83$

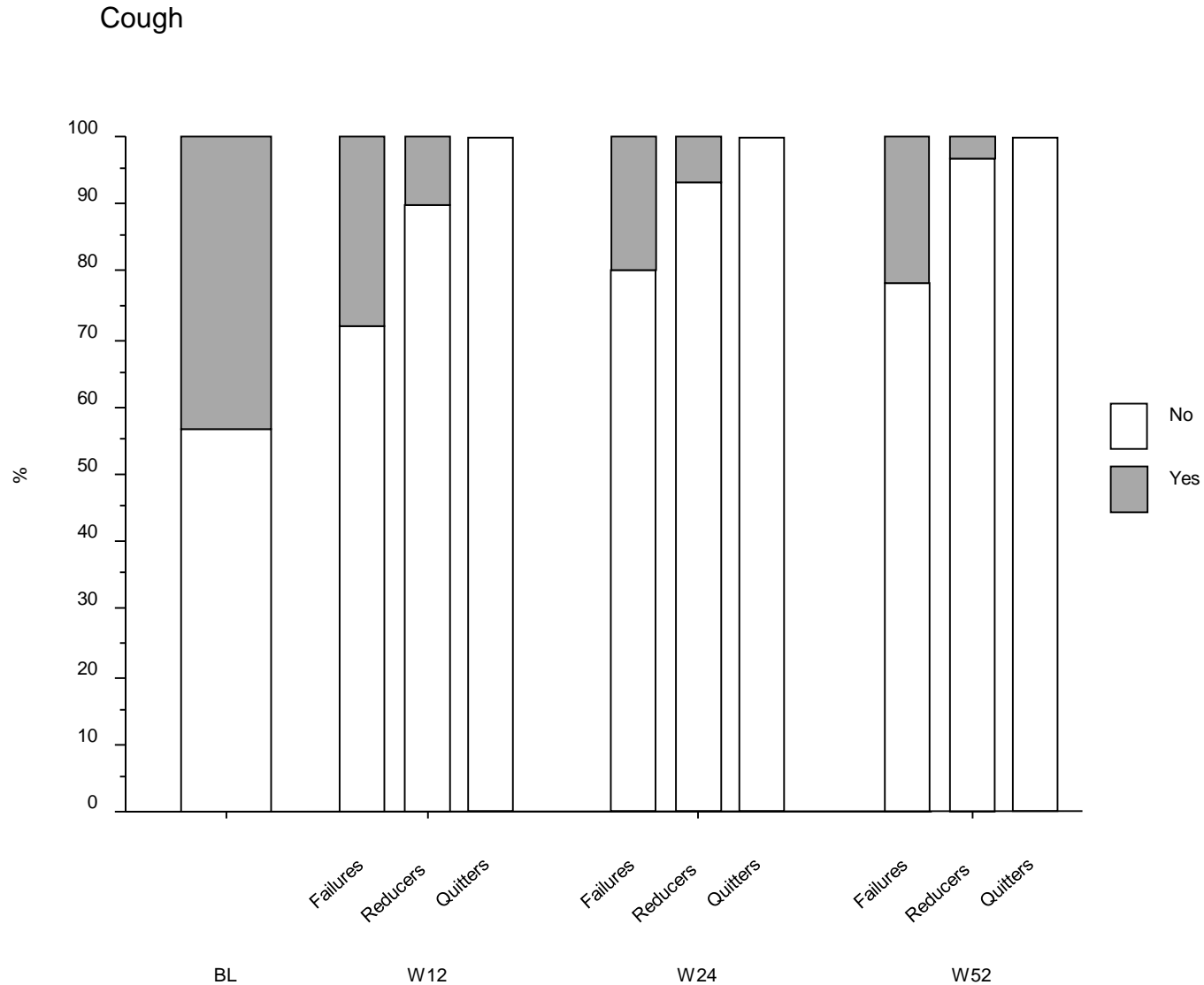


FEF_{25-75%}

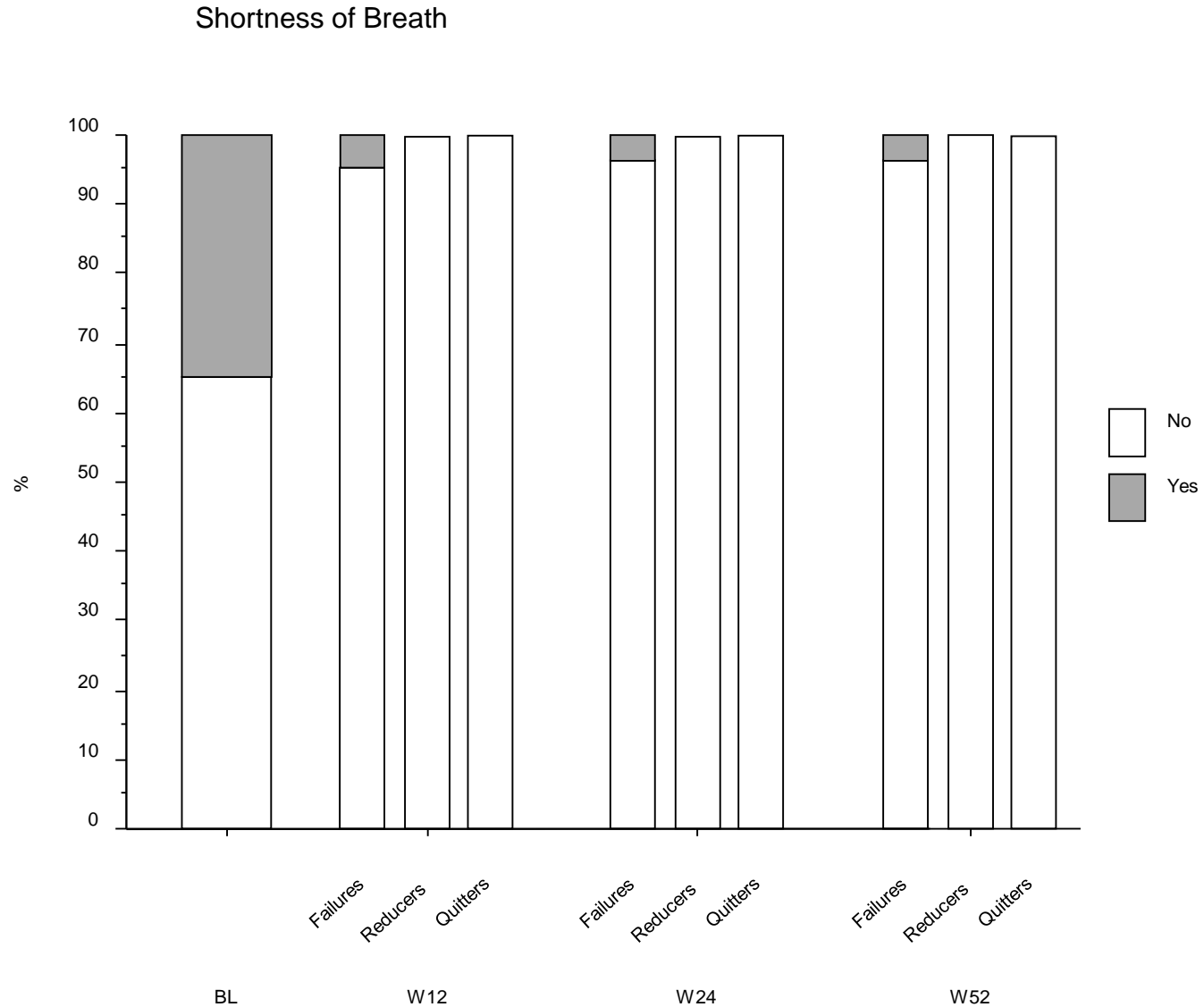
Between subject effects: $p=0.034$



Effect of abstinence/reduction on cough in smokers switching to ECs



Effect of abstinence/reduction on SOB in smokers switching to ECs



Article

Effect of Smoking Abstinence and Reduction in Asthmatic Smokers Switching to Electronic Cigarettes: Evidence for Harm Reversal

Riccardo Polosa ^{1,2,3,*}, Jaymin Morjaria ⁴, Pasquale Caponnetto ^{1,2}, Massimo Caruso ^{1,3},
Simona Strano ^{1,3}, Eliana Battaglia ^{1,3} and Cristina Russo ^{1,2,3}



- ECs are effective and safe in RCTs of “healthy” smokers
- Smoking abstinence by using ECs may improve respiratory function and symptoms
- No data about EC use in smokers with pre-existing disease
- We investigated changes in subjective and objective asthma outcomes in smoking asthmatics who switched to EC

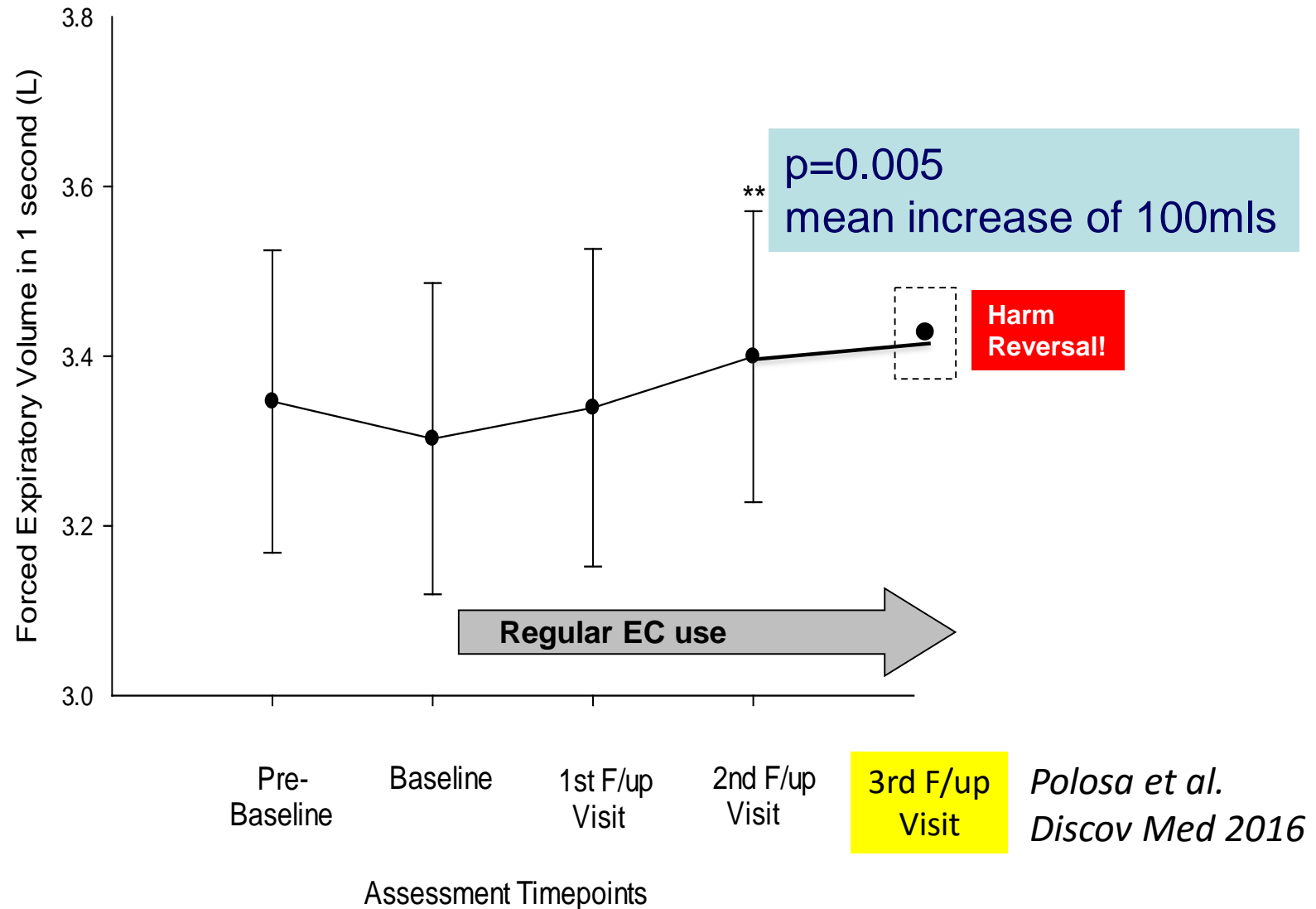


Persisting Long Term Benefits of Smoking Abstinence and Reduction in Asthmatic Smokers Who Have Switched to Electronic Cigarettes

RICCARDO POLOSA, JAYMIN B. MORJARIA, PASQUALE CAPONNETTO, MASSIMO CARUSO,
DAVIDE CAMPAGNA, MARIA DOMENICA AMARADIO, GIOVANNI CIAMPI, CRISTINA RUSSO,
AND ALFREDO FISICHELLA

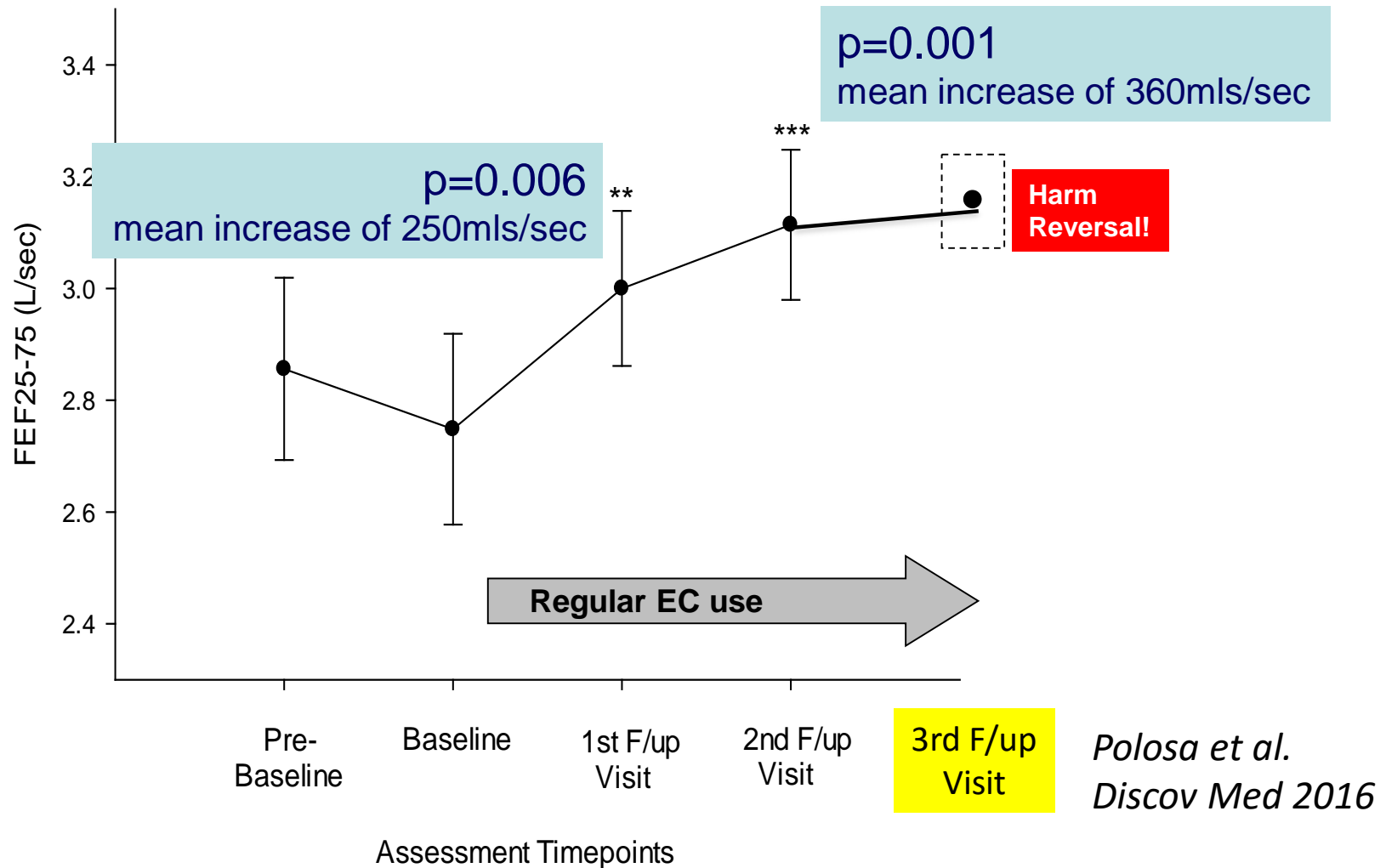
FEV1

Improvement from baseline to 24 months



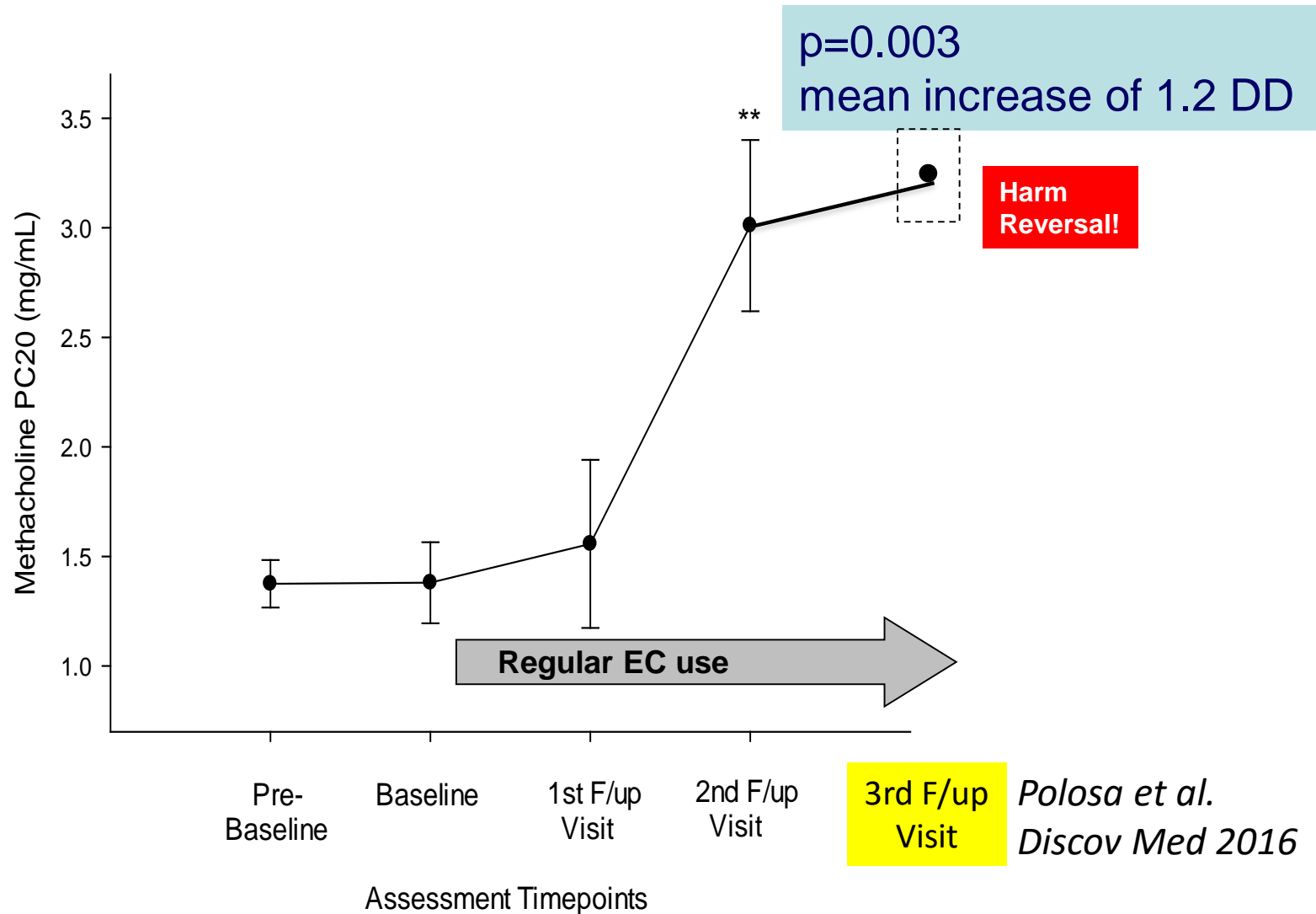
FEF25-75

Improvement from baseline to **24 months**



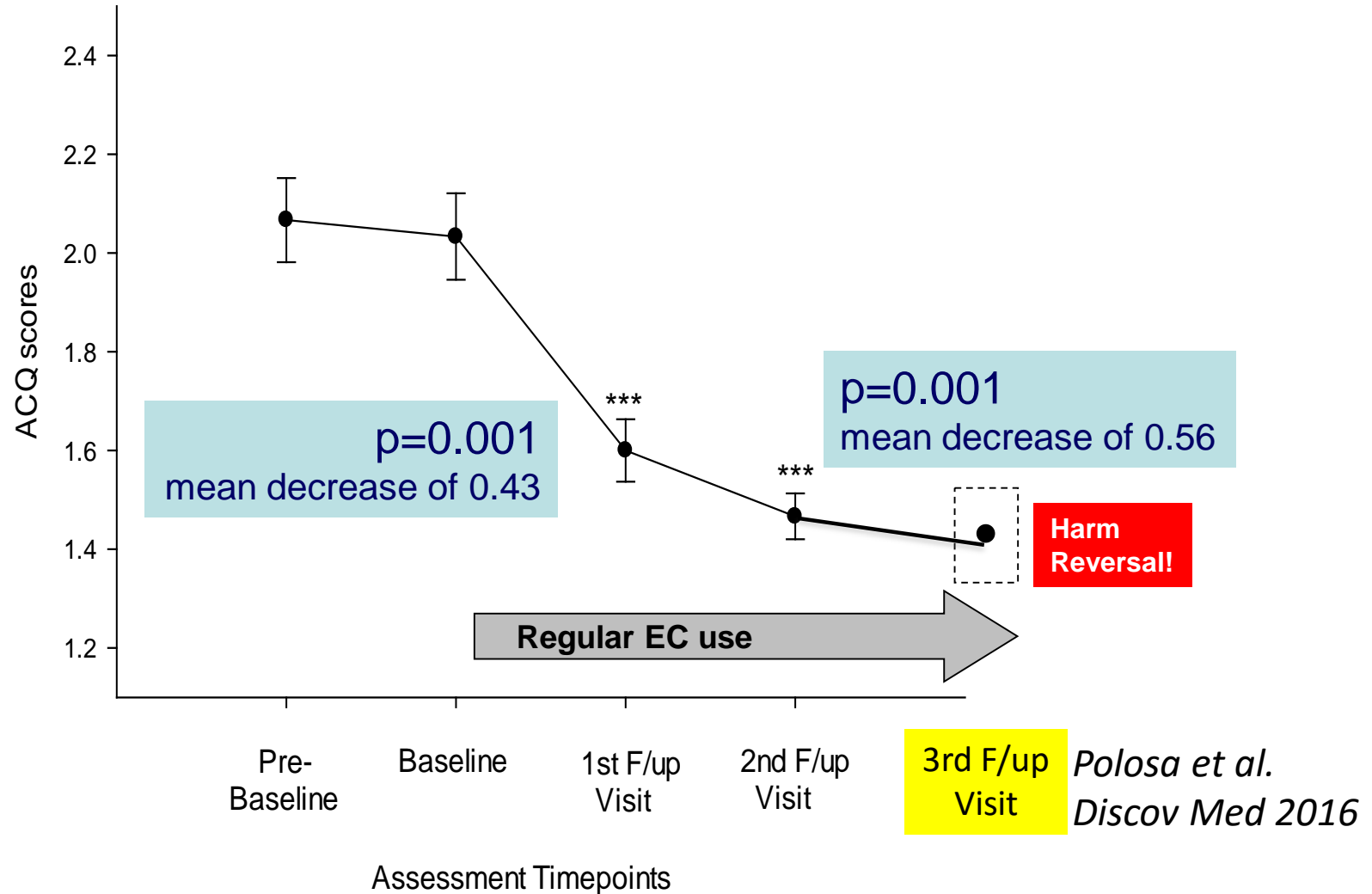
Methacholine PC20

Improvement from baseline to **24 months**



Juniper's ACQ

Improvement from baseline to **24 months**



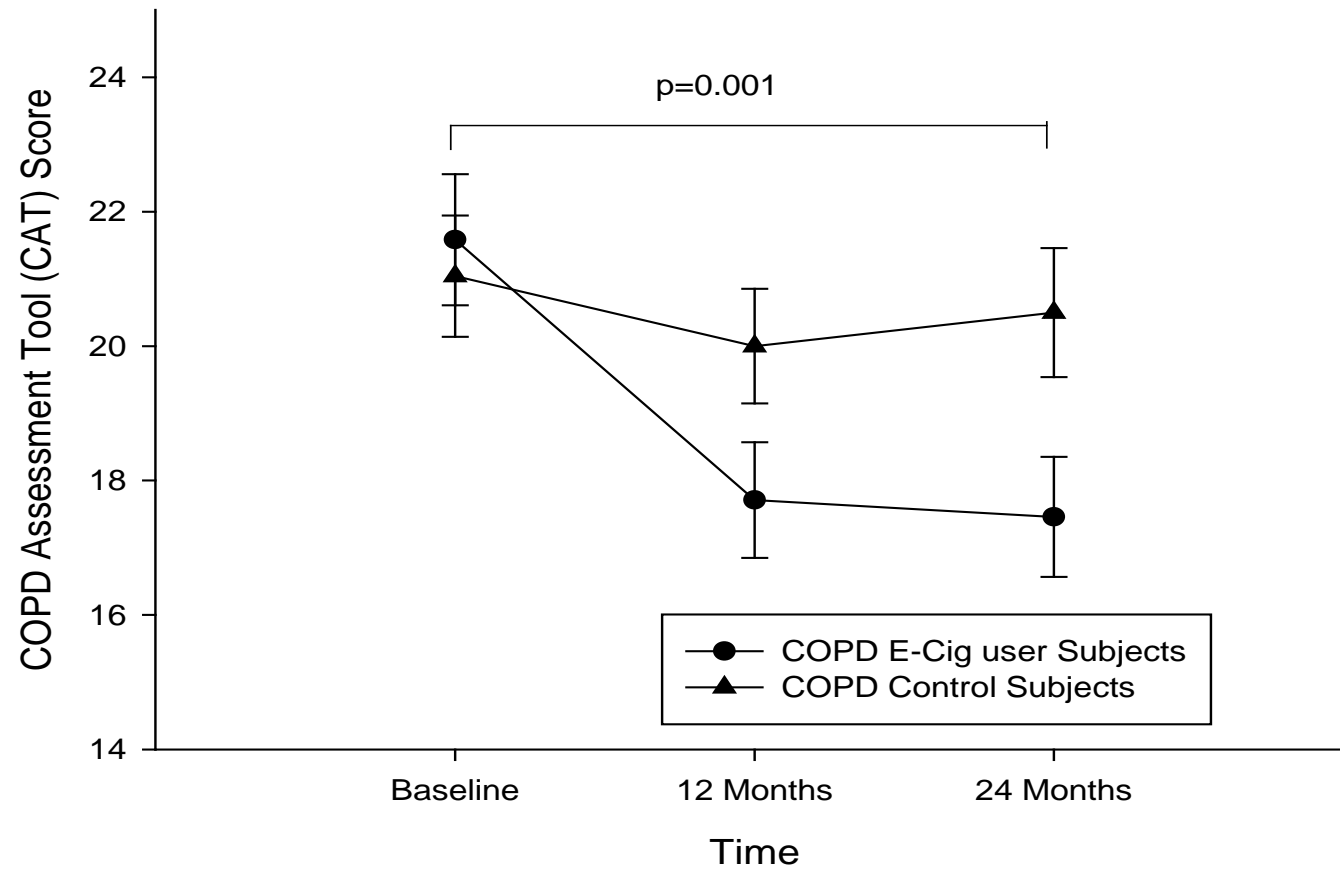
Vaping and asthma exacerbations

| Parameter | Baseline | 1 st follow-up visit | | 2 nd follow-up visit | | 3 rd follow-up visit w/o relapsers (24 months) | |
|----------------|----------------|---------------------------------|--------------------------------|---------------------------------|--------------------------------|---|--------------------------------|
| | N=18 | (6 months) N=18 | | (12 months) N=18 | | N=16 | |
| | | | <i>p value to Baseline</i> | | <i>p value to Baseline</i> | | <i>p value to Baseline</i> |
| Cigarettes/day | 21.9 (±4.5) | 5.0 (±2.6) | <0.001 | 3.9 (±1.0) | <0.001 | 3.5 (±1.22) | <0.001 |
| Exacerbations | 1.17 (±0.9) | 0.87 (±0.7) | 0.296 | 0.78 (±0.7) | 0.153 | 0.81 (±0.66) | 0.190 |

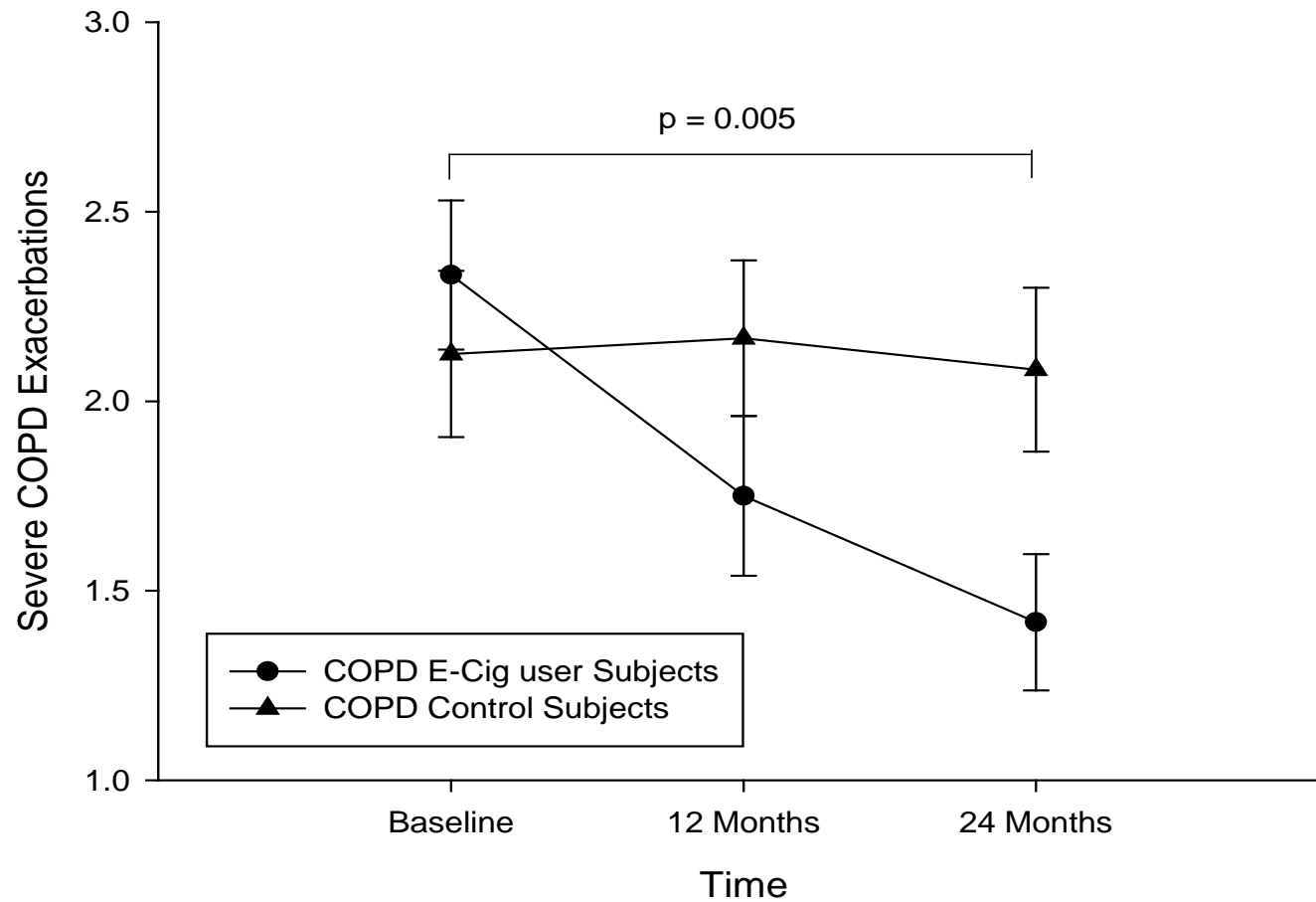
Frequent exacerbators (≥ 2 exacerbations; n=6) halved their exacerbations at both follow-up visits

Exacerbation rate increased from 0 at 12 months to 2 at 24 months in the two patients relapsing to tobacco smoking

COPD patients - QoL



COPD patients - Severe Exacerbations



RESPIRATORY SYMPTOMS IN E-CIG USERS

K. Farsalinos et al. Int. J. Environ. Res. Public Health 2014

| Side effects/accidents | Total (n = 19,353) | Current smokers (n = 3682) | Former smokers (n = 15,671) | Statistic | p value |
|------------------------|-----------------------|----------------------------------|-----------------------------------|-----------------|---------|
| | | Dual users | Single users | | |
| Asthma (N = 1173) | | | | | |
| Worse | 14 (1.1) | 5 (2.2) | 9 (0.8) | $\chi^2 = 27.3$ | <0.001 |
| Stable | 303 (23.2) | 78 (34.4) | 225 (20.8) | | |
| Improved | 856 (65.4) | 116 (51.1) | 742 (68.6) | | |
| COPD (N = 1062) | | | | | |
| Worse | 10 (0.8) | 4 (1.7) | 6 (0.6) | $\chi^2 = 9.5$ | 0.009 |
| Stable | 151 (12.7) | 39 (17.0) | 112 (11.7) | | |
| Improved | 901 (75.7) | 158 (68.7) | 743 (77.4) | | |

Take Home Message

- Improved lung function, respiratory symptoms, subjective/objective asthma outcomes;
- Improvements also reported in dual users;
- EC use unlikely to warrant significant respiratory concerns;
- An helpful alternative to cigarettes, even in smokers with asthma/COPD.

Areas of Exploration: Therapeutic Nicotine

- ❑ Treatment of tobacco dependence (i.e. Smoking cessation)
- ❑ Relapse prevention (protracted NRT use as smoking substitution is now recommended by several health authorities – e.g. MHRA, NICE)
- ❑ Management of several medical conditions:
 - ❑ Parkinson's disease (Thiriez et al., 2011)
 - ❑ Ulcerative colitis (Sandborn, 1999)
 - ❑ Major depression (McClernon, Hiott, Westman, Rosse, & Levin, 2006)
 - ❑ Schizophrenia (Barr et al., 2008)
 - ❑ Attention deficit hyperactivity disorder (Gehricke Hong, Whalen, Steinhoff & Wigal, 2009)
 - ❑ Mild cognitive impairment (Newhouse et al., 2012)
 - ❑ Others?

Understanding E-cigs Through the Lens of Pharmaceutical Respiratory Drug Delivery



Products that
are enjoyable



Products that are
not enjoyable

Understanding E-cigs Through the Lens of Pharmaceutical Respiratory Drug Delivery



- Replacement of syringes and pills (e.g. vaccination, insulin injection)
- Cannabidiols (CBD) for refractory pain control
- Improved medication adherence

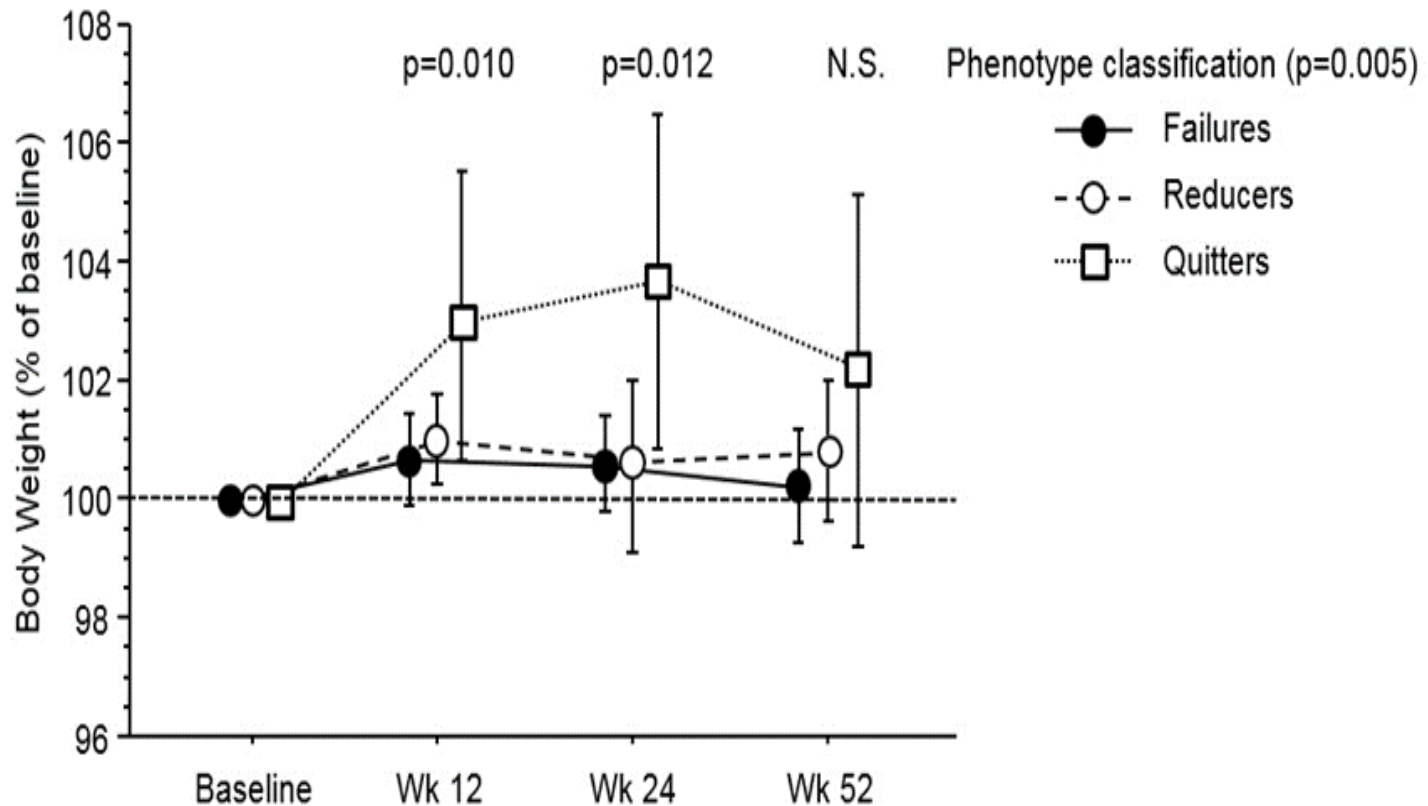


Why not making enjoyable, products (i.e. drugs) that are not enjoyable?

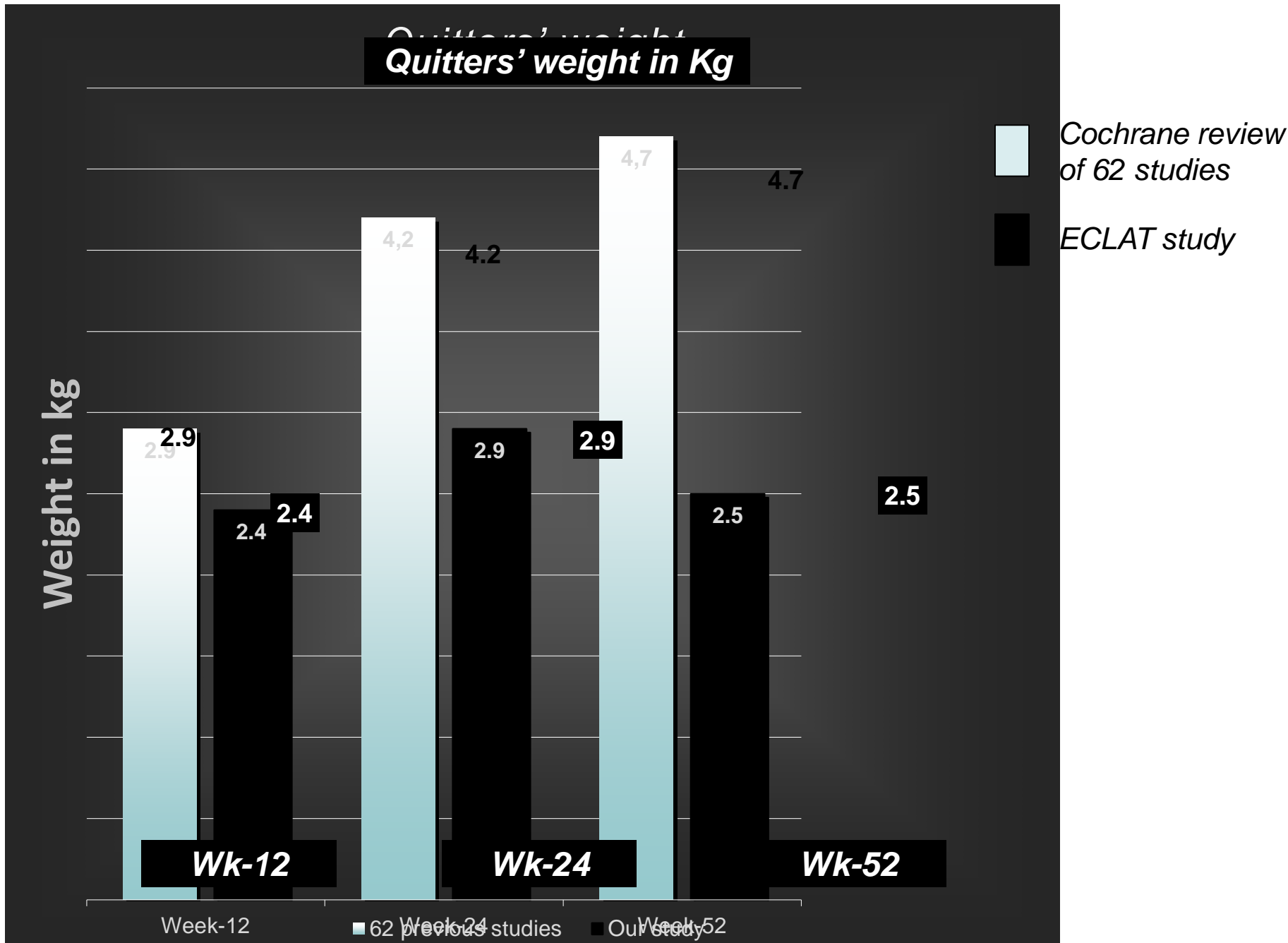
Areas of Exploration: Hedonistic/Wellness

Effect of smoking abstinence/reduction on weight changes in smokers switching to ECs

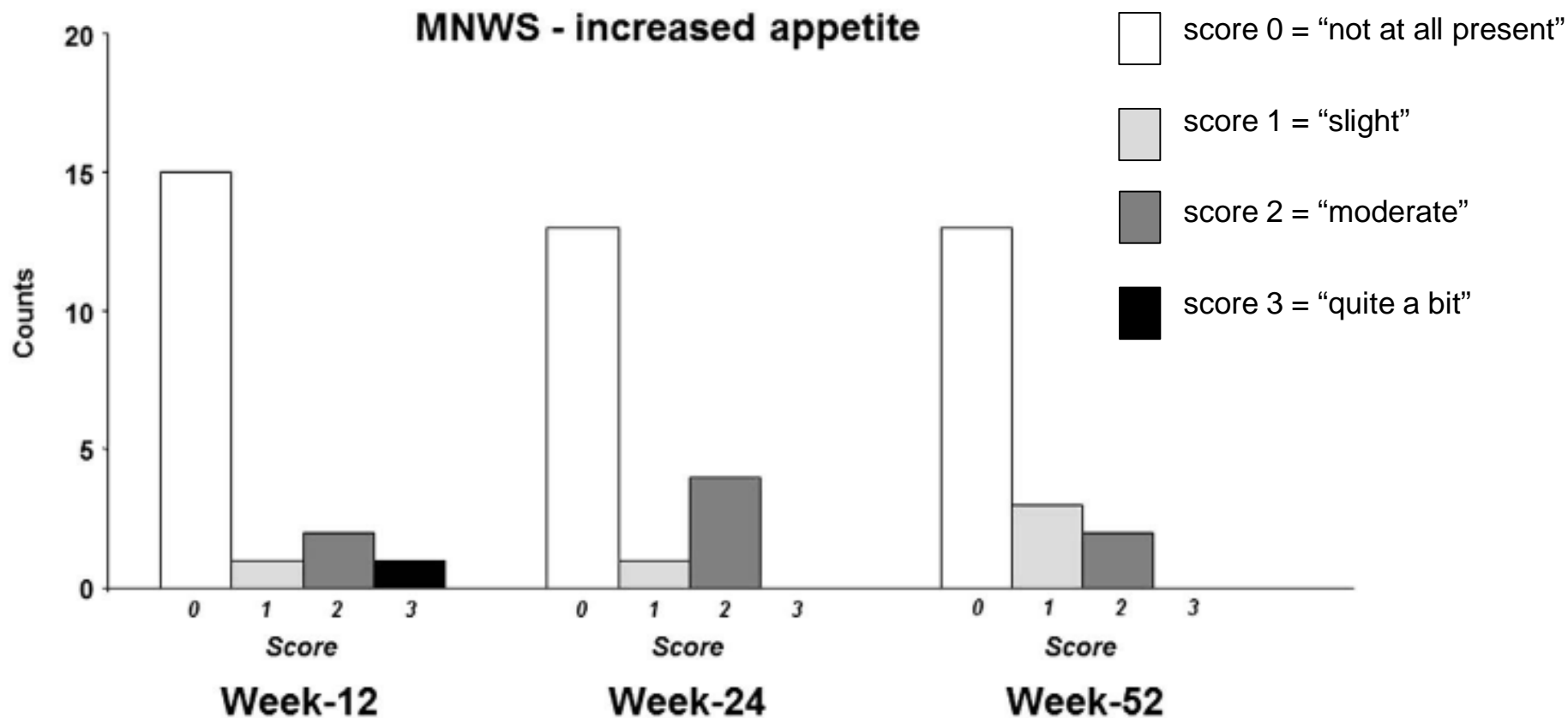
Post Cessation Weight Gain



Post Cessation Weight Gain in Quitters: Cochrane vs ECLAT



Effect of smoking abstinence/reduction on appetite score in smokers switching to ECs



Future Vaping Trends

- Weight loss programs (e.g. VaporDiet)
- Improved sleep/anxiety (e.g. NutriCigs)
- Energy boost (e.g. VitaCig)
- Memory boost
- Research programs addressing consumers hedonic and sensory characteristics
-

Vaping: Current and Emerging Views

Negative Aspects

Minimize Risk



Positive Aspects

Maximize Benefit

Janus head. Terracotta sculpture, from Vulci, II century BC (Rome, National Etruscan Museum of Villa Giulia).



**“E-cigs greatest health
advance since
vaccinations”**

*Prof. David Nutt
BBC Radio 5 live's Shelagh Fogarty
4 February 2014*

**Professor David Nutt,
Former government's chief drug adviser**