

# ***ASSESSMENT OF A TELEPHONE COUNSELING SMOKING CESSATION INTERVENTION IN THE LUNG CANCER SCREENING SETTING: A RANDOMIZED PILOT STUDY***

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# Background

- 2011: The National Lung Cancer Screening Trial
  - Screening by low-dose CT reduced mortality by 20%, compared to chest X-ray, for individuals at high risk for lung cancer
- 2013: USPSTF issued recommendation for lung screening
  - 30 pack years
  - Current smokers or former smokers who had quit within the past 15 years
  - 55-80 years old
- 2015: The Affordable Care Act and Medicare
  - both cover lung cancer screening and smoking cessation treatment
  - Medicare: 55-77 years of age, with stipulation for SDM and providing information about cessation interventions for current smokers is required
- Estimated that > 8 million adults in the US are eligible for screening and that screening may prevent 12,000 deaths/yr
  - Organizations endorse screening: ASCO, ACS, NCCN, ATS, etc.
  - **Approximately 50% of individuals undergoing screening are current smokers**

# Integrating Smoking Cessation within Screening Programs

- **Adding smoking cessation to screening:**
  - Further reduces mortality due to lung cancer: Quitting between 55-64 years gains 4 years of life compared to those who continue to smoke
  - Improves cost-effectiveness of lung screening, demonstrated by modeling studies
- **Joins disease prevention (smoking cessation) with early detection (CT screening) in a setting that, by definition, draws older, long-term smokers:**
  - Many of these current smokers are not actively seeking help with quitting,
  - Screening provides access to an otherwise difficult to reach group
- **A small increase in cessation will have a very large public health benefit:**
  - Given the large number of screening-eligible individuals who are current smokers

# Teachable Moment of Lung Cancer Screening

- The ‘teachable moment’ after cancer screening may increase intention to quit and cessation
  - Some observational studies have shown that abnormal screens increase motivation while normal screens decrease motivation
  - However, not all studies have found this association
  - This relationship may depend on:
    - severity of the screening result
    - amount of time between the screening result and when smoking status is measured
    - adequate power
- A cessation intervention may capitalize on this potential momentum created by lung cancer screening
  - However, there are no clinical guidelines or evidence-based protocols with demonstrated effectiveness in this setting.

# Observational studies of Smoking Cessation in the context of Lung Cancer Screening Randomized Trials

Reference	Subjects	Method	Cessation Results
Taylor, Cox, Zincke, Mehta, McGuire, & Gelmann (2007). <u>Lung Cancer</u>	LSS: N =144 NLST: N=169 <ul style="list-style-type: none"> <li>ages 55-74</li> <li>current and former smokers</li> </ul>	Telephone interview at <ul style="list-style-type: none"> <li>Pre-screening</li> <li>Post-screening (3-4 weeks post-receipt of results)</li> </ul>	Self-reported Quit Rate: LSS: 6.6%; NLST: 7.2% Relapse Rate: LSS: 4.1%; NLST: 4.7% Readiness to quit: (p = .02) abn result: more ready norm result: less ready
Barry, Tammemagi, Penek, Kassin, Dorfman, Riley, Commin, Taylor (2013). <u>JNCI</u> .	PLCO trial (chest x-ray vs UC): <ul style="list-style-type: none"> <li>31,694 former smokers</li> <li>6,807 current smokers</li> </ul>	Questionnaire at <ul style="list-style-type: none"> <li>trial enrollment</li> <li>follow-up at 4-14 years post-enrollment</li> </ul> <p>Developed prediction models of relapse and cessation.</p>	Relapse: 3.3% Quit: 34.8% <ul style="list-style-type: none"> <li>Neither trial arm nor the lung screening result were related to smoking outcomes</li> </ul>
Tammemagi, Berg, Riley, Taylor (2014). <u>JNCI</u>	NLST trial: <ul style="list-style-type: none"> <li>16,265 current smokers</li> </ul>	Annual self-reported smoking status assessed; Prediction models of cessation developed	Cessation was strongly associated with the amount of abnormality observed in the previous year's screening result (P<0.0001).

## Randomized cessation intervention studies conducted within lung cancer screening programs

Reference	Intervention	Cessation Results
Marshall et al. (2016) <u>Nic Tob Res.</u> (Australia)	<ul style="list-style-type: none"> <li>• Single session in person counseling on screening day (N=28)</li> <li>• Print materials + quitline contact information (N=27)</li> </ul>	1 year self-report: <ul style="list-style-type: none"> <li>• Intervention: 14.3%</li> <li>• Control: 18.5%</li> </ul>
Ferketich et al. (2011); <u>Lung Cancer</u> (Ohio State Univ.)	12 telephone counseling sessions: <ul style="list-style-type: none"> <li>• pre-CT (N = 9)</li> <li>• post-CT (N=9)</li> </ul>	4 mos: <ul style="list-style-type: none"> <li>• pre-CT: 33.3%</li> <li>• post CT: 22.2%</li> </ul> 6 mos: <ul style="list-style-type: none"> <li>• pre-CT: 22.2%</li> <li>• post-CT: 11.1%</li> </ul>
Van der Aalst et al (2012). <u>Lung Cancer</u> (Males Dutch/Belgian RCT)	<ul style="list-style-type: none"> <li>• Standard brochure (N=642)</li> <li>• Tailored web-based intervention (N=642);</li> </ul>	2 year follow-up: <ul style="list-style-type: none"> <li>• brochure: 15.6%</li> <li>• web: 12.5%</li> </ul>
Clark et al (2004). <u>Lung Cancer</u> (Mayo Clinic)	<ul style="list-style-type: none"> <li>• Standard self-help cessation information (N = 86)</li> <li>• Self-help Internet resources (N = 85)</li> </ul>	1 year follow-up: <ul style="list-style-type: none"> <li>• Standard: 10%</li> <li>• Internet 5%</li> </ul>

# Rationale for Testing the Impact of a Telephone Counseling Cessation Intervention

- Literature on effectiveness of telephone counseling with:
  - older smokers
  - non-treatment seeking smokers
  - those not ready to quit
  - Intensive enough to assist those who are ready to quit
- Most current smokers undergoing screening are not seeking a cessation intervention and are not ready to quit
  - In person counseling is not likely to have a high attendance
  - Including cessation medication was not feasible in terms of management by the screening sites
- An intervention that is scalable across screening centers
- Pilot study of 6 current smokers undergoing screening at GU (Hagerman et al., 2015)
  - 3 telephone counseling sessions
  - 4/6 self-reported quitting; 3/6 provided biochemical verification at 1 month follow-up

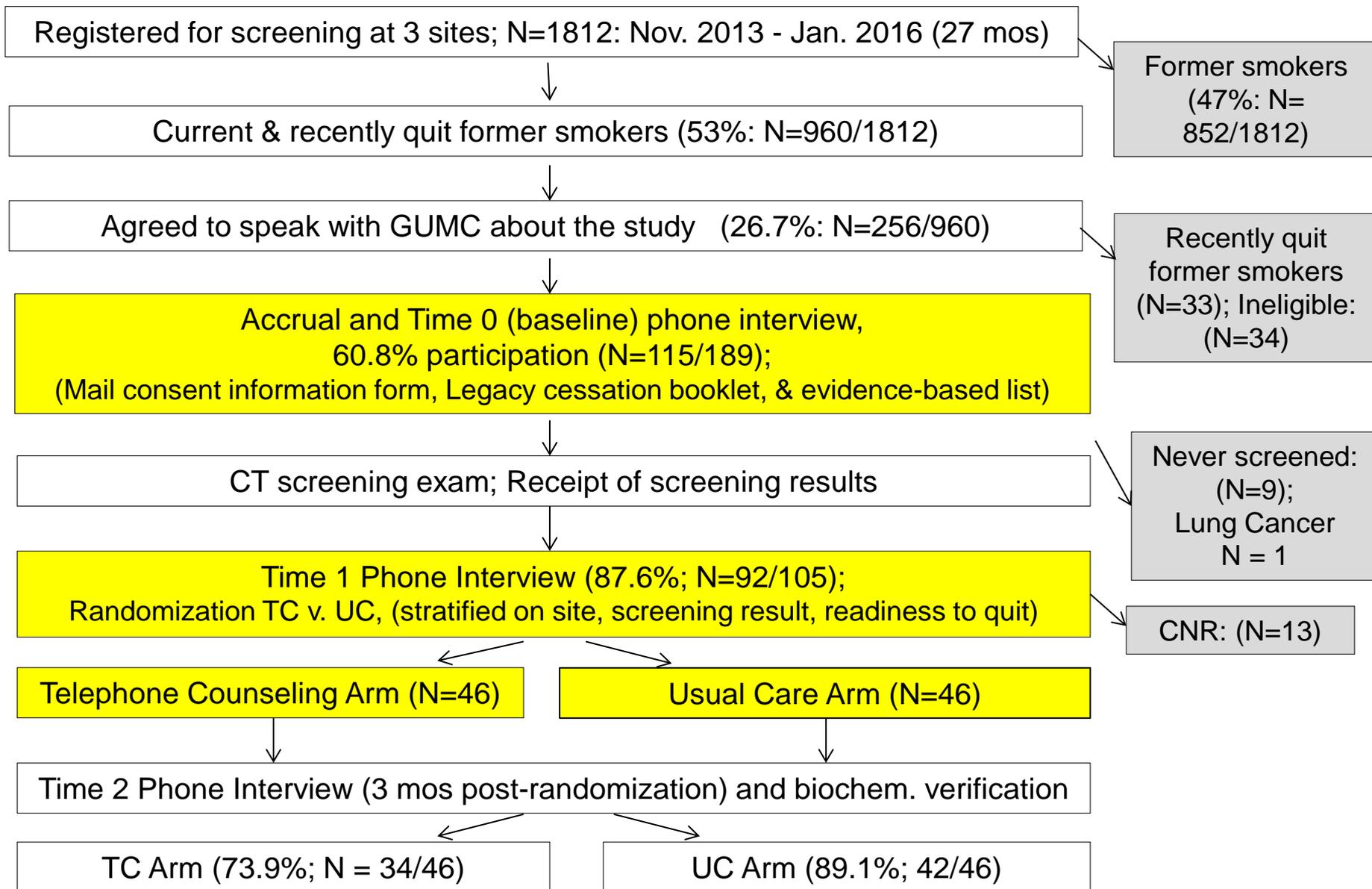
# Specific Aims

- 1) To conduct a two-arm randomized cessation intervention trial with current smokers scheduled to undergo lung cancer screening
  - Usual Care: Received a list of evidence-based cessation resources
  - Telephone Counseling: Received the list of resources plus up to 6 sessions with a trained telephone counselor
- 2) To explore whether the screening result moderated the impact of the intervention on cessation

# Inclusion Criteria

- Current smoker
- 55-80 years old
- 30+ pack year smoking history
- Enrolled for screening at one of the 3 sites
- Baseline telephone interview conducted prior to screening
- English-speaking
- Readiness to quit was not an inclusion criterion— all smokers encouraged to participate

# Study Flow Chart



# Usual Care arm

## List of evidence-based resources:

- 1) website (Legacy's [www.BecomeAnEx.org](http://www.BecomeAnEx.org))
- 2) print (Legacy's BecomeAnEx booklet)
- 3) telephone quitline (1-800-QUIT-NOW)
- 4) CDC's text messaging: <http://smokefree.gov/smokefreetxt>
- 5) iPhone and Android Livestrong MyQuit App
- 6) Local, in person cessation counseling resources

## Resources for Reducing Dependence on Tobacco



for individuals in the MedStar Lung Cancer Screening Program

### WANT TO QUIT SMOKING OR STAY QUIT?

We have many ways that can help you!

#### INTERACTIVE WEBSITE

[BecomeAnEx.org](http://BecomeAnEx.org)

#### PRINT MATERIALS

BecomeAnEx booklet for current smokers

#### TELEPHONE QUITLINE

1-800-QUIT-NOW (1-800-784-8669)

#### TEXT MESSAGING

Sign up for text message reminders and encouragement at <http://smokefree.gov/smokefreetxt>

#### IPHONE AND ANDROID APP

The LIVESTRONG My Quit App is a free smartphone app that allows you to track your quitting and cravings, and offers encouragement through the quitting process

#### LOCAL CESSATION COUNSELING

The list includes group and individual cessation counseling options in the DC, Maryland and Virginia areas



# Telephone Counseling arm:

- 1) List of evidence-based resources
- 2) Up to six 15-minute, manualized telephone sessions with an ATTUD-trained tobacco treatment specialist
- 3) Sessions tailored on intention to quit, nicotine dependence, screening result:
  - Motivational interviewing for those not ready to quit
  - Encouragement to consider using NRT when appropriate, and to talk with PCP re Chantix & Zyban
  - The screening result framed as a primary motivator to quit
    - education about benefits of quitting smoking for older smokers
    - abnormal results: quitting now will reduce the chance of having a worse result next year
    - normal results: challenge thoughts that reflected minimization of the need to quit: not a 'clean bill of health'

# Baseline Demographic Characteristics

	Usual Care (N=46)	Telephone Counseling (N=46)
Sites: Lahey Hospital MC	71.7%	76.1%
Georgetown Univ MC	15.2%	15.2%
Hackensack Univ MC	13.0%	8.7%
Gender (% female)	58.7%	54.3%
Age (M, SD)	60.1 (5.7)	60.4 (5.1)
Race (% white)	93.5%	93.5%
Education: ≤ High School	26.1%	41.3%
Some College	43.5%	30.4%
≥ College grad	30.4%	28.3%
Marital Status (% married/living as)	43.5%	41.3%
Employment (% employed FT)	32.6%	41.3%
Tobacco-related comorbidities: 0	21.7%	34.8%
1	39.1%	37.0%
2+	39.1%	28.3%

No significant group differences

# Baseline Tobacco Use Characteristics

	Usual Care (N=46)	Telephone Counseling (N=46)
Cigarettes per day: <10	26.1%	30.4%
11-19	21.7%	32.6%
20	30.4%	23.9%
21+	21.7%	13.0%
Pack Years (M, SD)	50.3 (20.4)	43.8 (23.7)
Fagerstrom (M, SD)	4.6 (2.0)	4.1 (1.8)
24h quit attempts in past year	5.7 (18.0)	7.3 (29.5)
Readiness to Quit: Not Ready	47.8%	56.5%
Ready- Next 6 mos	21.7%	13.0%
Ready- Next 30 days	30.4%	30.4%
Other tobacco use in past 30 days		
pipe	0.0%	0.0%
cigar	4.3%	4.3%
tiparillos	0.0%	0.0%
smokeless tobacco	0.0%	0.0%
e-cigarettes	16.3%	4.4%

No significant group differences

# Baseline: Lung Screening and Lung Cancer Characteristics

	Usual Care (N=46)	Telephone Counseling (N=46)
Lung Screening history (% yes)	47.8%	39.1%
Primary reasons for screening		
Doctor recommendation	82.6%	82.2%
Peace of mind about lung cancer	80.4%	84.4%
Personal History of Cancer (e.g., skin, prostate, breast)	26.7%	26.7%
Family History of Lung Cancer	34.8%	44.4%
Perceived worry about developing LC (% very much/extremely)	45.6%	44.5%
Perceived risk about developing LC (% higher/much higher risk than others)	50%	48.9%

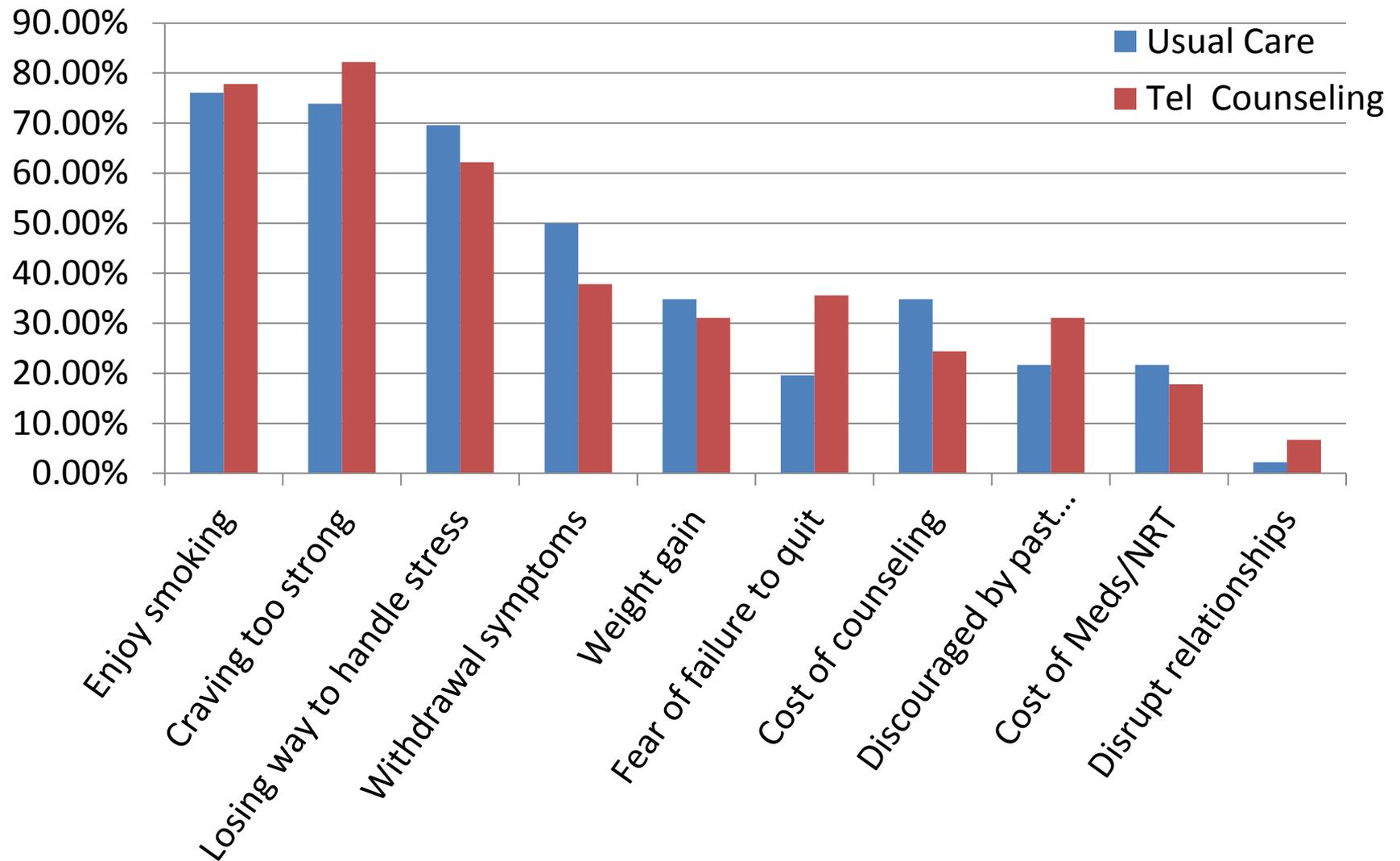
No significant group differences

# Lung Cancer Screening Results (NLST definition)

	Usual Care (N = 46)	Telephone Counseling (N=46)
Normal	21 (45.7%)	24 (52.2%)
Minor Abnormality (lung nodule < 4mm)	2 (4.3%)	0 (0%)
Not Suspicious for LC but Other Abnormality (e.g., emphysema, coronary calcifications)	14 (30.4%)	13 (28.3%)
Suspicious for LC ( $\geq$ 4mm)	9 (19.6%)	9 (19.6%)

$\chi^2 = 2.2$  (df=3),  $p > .50$

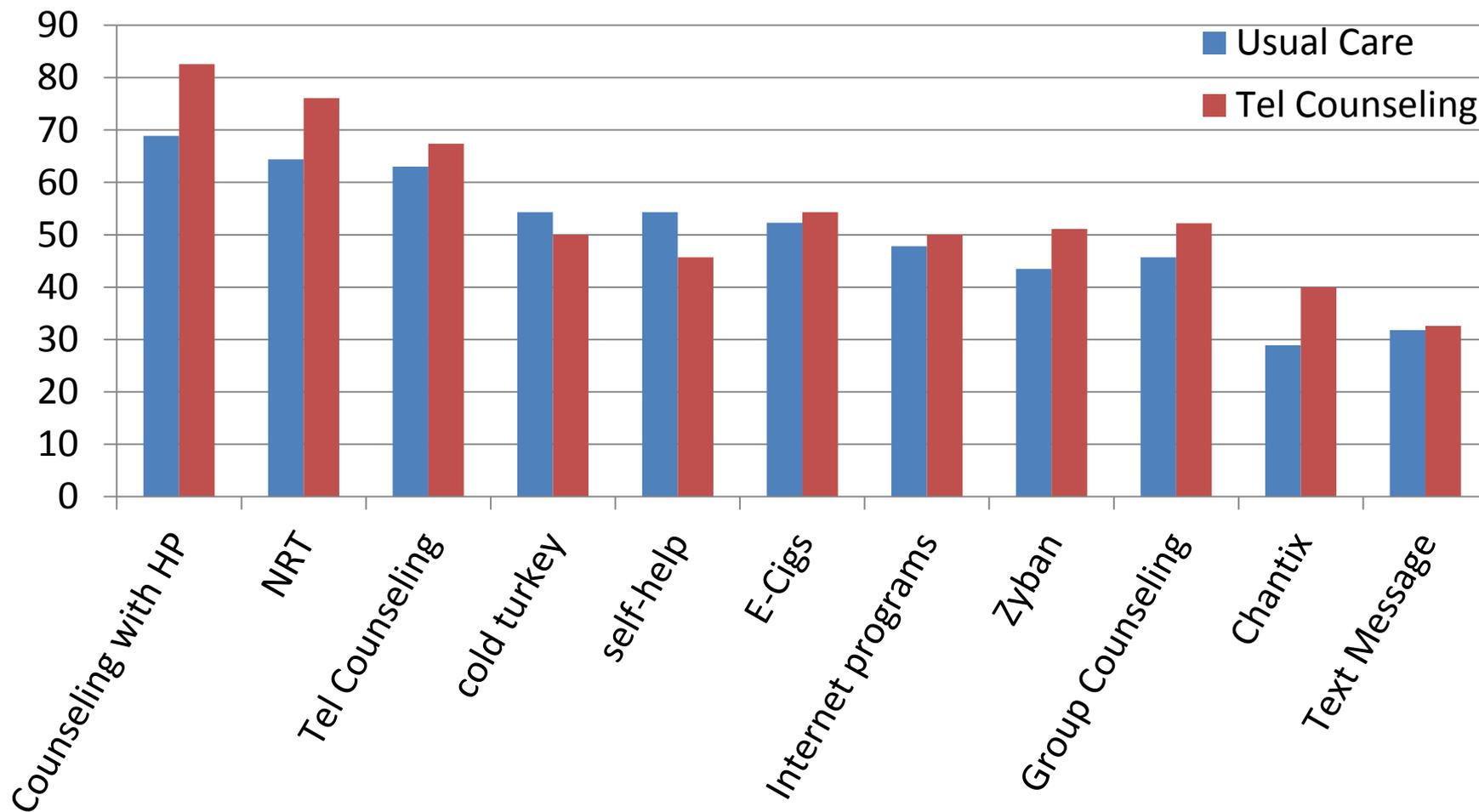
# Baseline: Barriers to Quitting (% yes)



No significant group differences

# Baseline: Interest in Using Cessation Interventions

(% definitely/possibly)



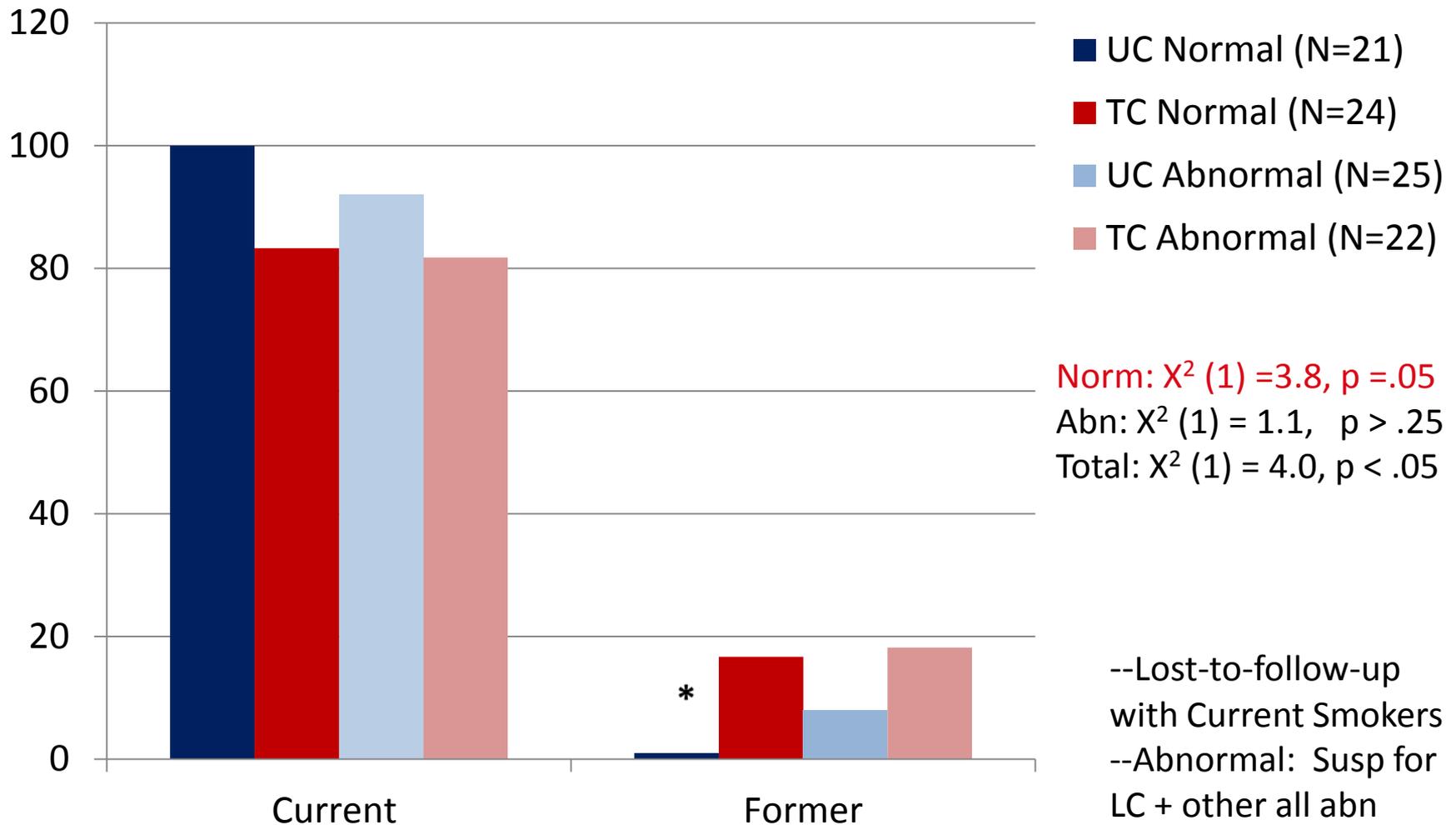
No significant group differences

## Outcomes at 3-month follow-up (T2)

	Usual Care	Tel. Counseling
Self-reported 7 day pp cessation (intent to treat analysis)	9/46 (19.6%)	10/46 (21.7%)
Biochemically verified cessation* (intent to treat analysis) *p < .05	2/46 (4.3%)	8/46 (17.4%)
≥ One 24h quit during the study	25/46 (54.3%)	23/46 (50.0%)
Cigs per day: current smokers w. T2		
<10	14/33 (42.4%)	13/24 (54.2%)
11-19	7/33 (21.2%)	6/24 (25.0%)
20	10/33 (30.3%)	3/24 (12.5%)
21+	2/33 (6.1%)	2/24 (8.3%)
Readiness to Quit: curr smokers w. T2		
Not Ready to Quit	17/33 (51.5%)	12/24 (50.0%)
Ready to Quit—next 6 mos.	9/33 (27.3%)	7/24 (29.2%)
Ready to quit—next 30 days	7/33 (21.2%)	5/24 (20.8%)
	9 former; 4 lost to f-up;	10 former, 12 lost to f-u;

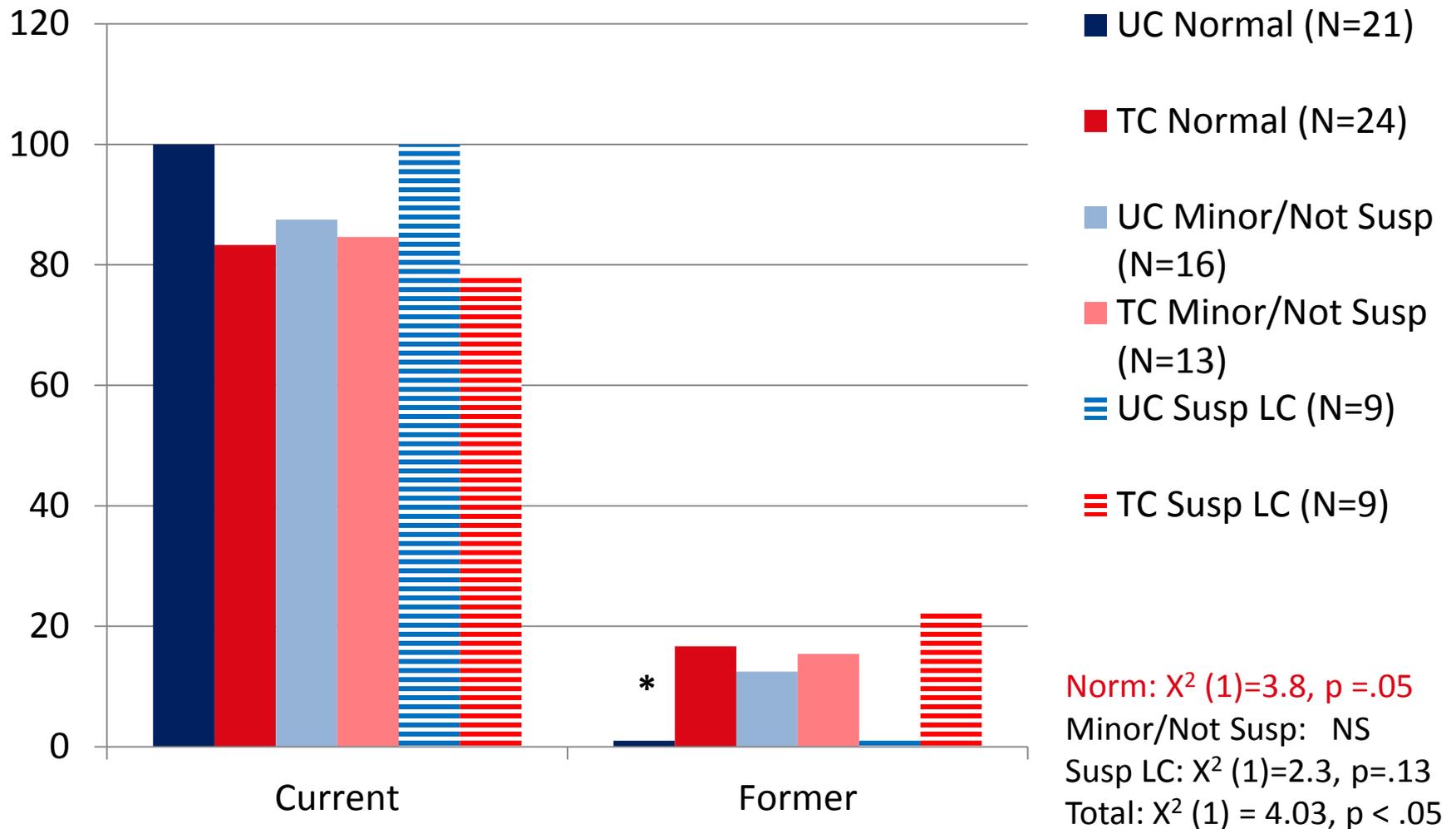
# Impact of Screening Result (2-level) on Biochemically Verified Cessation Status at T2

(3 mos post-randomization; intent to treat analysis)



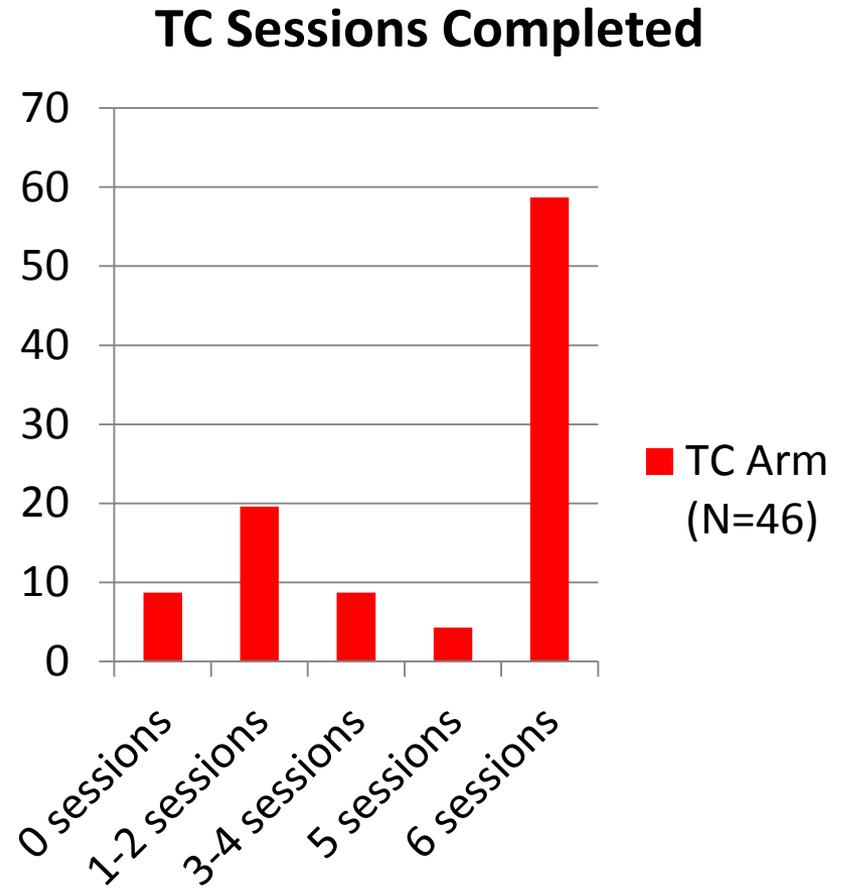
# Impact of Screening Result (3-level) on Biochemically Verified Cessation Status at T2

(3 mos post-randomization; intent to treat analysis)



# Process Outcomes in TC Arm

- An average of 4.3 (SD=2.3) of 6 TC sessions completed
- More calls positively associated with more quit attempts ( $p<.01$ ) and the verified quit rate ( $p<.05$ )
  - not adjusted for readiness to quit at baseline;
- Over one-half of self-reported former smokers (T2) had used NRT during the study:
  - 55.6% UC and 60% TC



# Summary

- Preliminary evidence suggesting that telephone-based cessation intervention is feasible and efficacious in LCS settings
- If TC result is replicated and cost-effective in a larger study, it is scalable via existing quitlines, thereby potentially reaching a large number of current smokers.
- Screening result moderated the impact of study arm on cessation, suggesting the importance of intervening following normal results and capitalizing on the motivation generated by results suspicious for LC.
- Biochemical verification appears to be necessary, based on the different findings of self-report vs. biochemically verified quit rates.

# Limitations

- Small sample size with limited power to detect the impact of TC on other smoking-related outcomes
- Brief follow-up of 3 months
- Majority of sample was white, reflecting the state of many LCS programs at present

# Next Steps

- Seek to improve the TC intervention, while maintaining scalability using quitlines
- Assess the impact of different levels of intensity of telephone counseling on cessation outcomes
- Add delivery of NRT to telephone counseling
- Involve the referring physician in cessation progress, particularly for those who are unable to quit following the TC intervention
- Brief advice on the day of the screening exam
- Access all persons undergoing screening in order to enroll all current smokers in the intervention

# Collaborators

- Georgetown Lung Cancer Screening Program:
  - Eric Anderson, MD and Jenna Kramer, NP
- Lahey Hospital Lung Screening Program:
  - Andrea McKee, MD and Shawn Regis, PhD
- Hackensack University MC Lung Screening:
  - Harry Harper, MD and Michael Ramsaier
- Georgetown/Lombardi:
  - Charlotte Hagerman, BA, Cassandra Stanton, PhD, George Luta, PhD, Paula Bellini, MA, Riley Zinar, and Daniel Leigh, BS
- Truth Initiative (Legacy):
  - David Abrams, PhD, Ray Niaura, PhD