

A randomized trial of a novel patient-centered preventive intervention to reduce alcohol use among medically vulnerable youth – confirming a theory of change

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Acknowledgments and Plan

- No conflicts to report
 - Funding by Conrad N Hilton Foundation (GRANT #__)
 - Informed by NIAAA ____
1. Background and definitions
 2. Development of an alcohol use intervention tailored to youth with a chronic illness
 3. Preliminary results
 4. Next steps
 5. Q & A



...I didn't want to take [my medicine] Saturday morning because I planned on drinking...And then I woke up Sunday morning, like the morning after I drank and then I took it – like a little bit in the afternoon – because I couldn't really stand the pain.

Female with juvenile idiopathic arthritis, age 16



Chronic Medical Condition Model



~25% of US youth living w/chronic illness

CMCs heterogeneous in origin, mechanism and share constellation of features that may be affected by alcohol use

- Ongoing medication use
- Monitoring with medical testing
- Need for self-care/management
- Vulnerability to behaviors & exposures correlate w/AOD use

Emerging epidemiology of alcohol use among youth with a chronic medical condition (YCMC) – no prevention models

Cohort study N=505 YCMC (RR 76%; 52% female, 75% white)¹

- 36.5% past year drink, of which 37% binged
- Drinkers ~2X as likely to report recent regular non-adherence
- 86% taking alcohol-interactive (AI) medications²
- Drinking less likely and lower total consumption among YCMC taking AI medications; partially mediated by worry about medication interference

National Longitudinal Study N=2,719 interviewed in ≥ 1 (up to 5) times between ages 12 - 26 years for PSID³

- YCMC as likely as healthy peers to report ever drinking in early/mid-adolescence, thereafter more likely
- YCMC more likely to report problem/heavy use in early/mid-adolescence

¹Weitzman et al, Pediatrics 2015, ²Weitzman et al., Pediatrics 2018; Wisk and Weitzman, AJPM, 2016.

Trial of a novel brief intervention to prevent and reduce alcohol use for YCMC

Develop: patient-centered, grounded in experience of condition, concerns and daily life (affective + medical science)

Evaluate: using RCT

Delivery: self-administered, tablet in subspecialty care

Eligibility: N=450 BCH patients, ages 14-17 years, English speakers, diagnosed for >1 year with JIA, or T1D, or IBD

Measures: baseline in clinic, 6 & 12 month e-survey; intervention post-test impacts of viewing the intervention

IRB: patient assent, safety protocol

Model – persuasion (**affective appeal**) + knowledge (**medical science**) to encourage positive behavior

Knowledge (% correct)

Regular blood tests help your doctor monitor your liver function and identify problems before they get serious. Alcohol can cause abnormal results on liver blood tests, making it difficult for your doctors to understand how you're doing.



Alcohol use

Perceived risk (ordered scale)

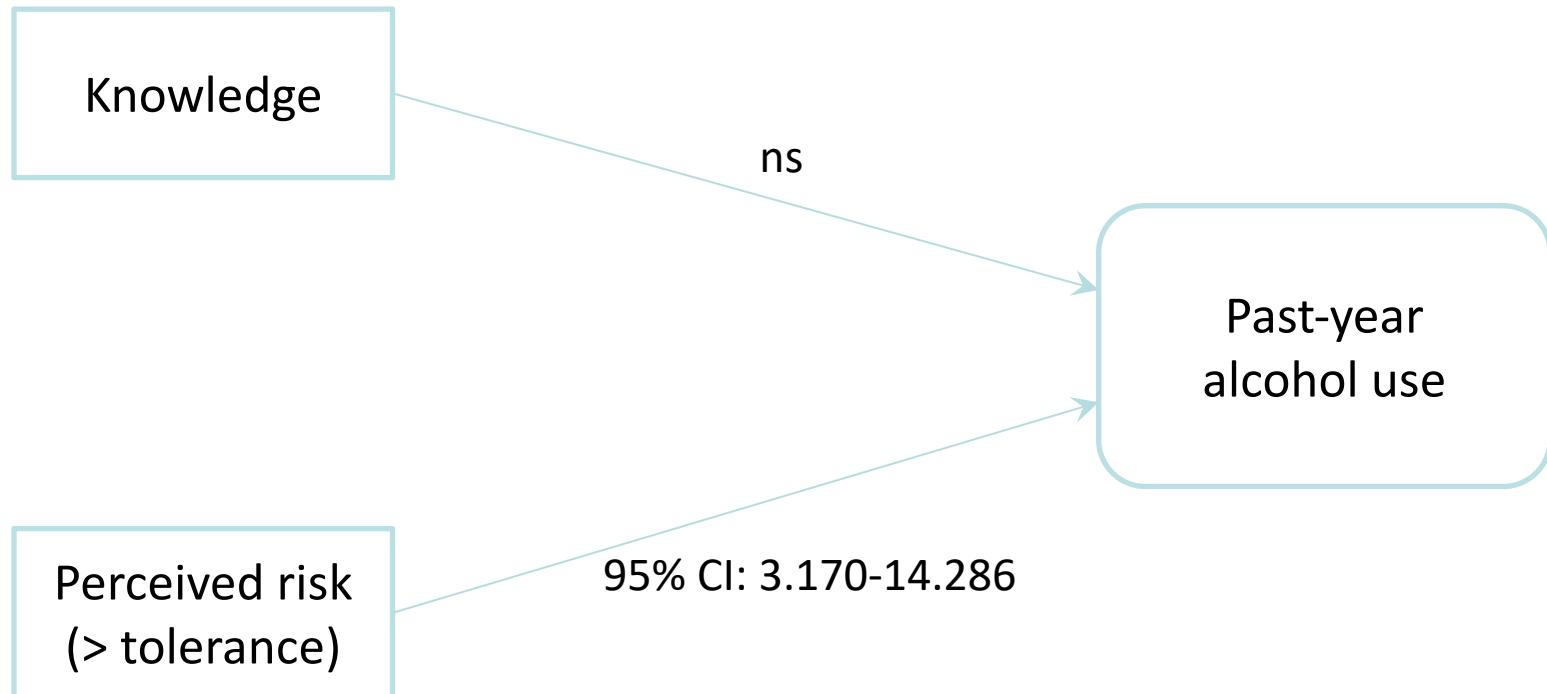


Sample characteristics, total and by trial arm

	Total		Randomization group				p-value
	<i>(N=400)</i>		<i>Control</i>		<i>Intervention</i>		
	N	%	N	%	N	%	
Age (mean, sd)	16.1	1.4	16.1	1.4	16.0	1.5	0.4768
Gender							
Male	199	49.9%	99	50.3%	100	49.5%	0.8811
Female	200	50.1%	98	49.7%	102	50.5%	
Race/Ethnicity							
White non-Hispanic	325	81.3%	158	79.8%	167	82.7%	0.4613
Other race/ethnicity	75	18.8%	40	20.2%	35	17.3%	
Depression symptoms	19	4.8%	8	4.1%	11	5.4%	0.5235
Anxiety symptoms	34	8.5%	15	7.6%	19	9.5%	0.5118
Parent college degree	291	73.7%	132	67.7%	159	79.5%	0.0077
Clinic							
Endocrinology	196	49.0%	98	49.5%	98	48.5%	0.981
Rheumatology	102	25.5%	50	25.3%	52	25.7%	
Gastroenterology	102	25.5%	50	25.3%	52	25.7%	
Past-year alcohol use	98	24.6%	43	21.7%	55	27.5%	0.1806
Alcohol knowledge - % correct (mean, sd)	63.7	26.5	63.4	26.0	64.0	27.0	0.8081
High risk intolerance (any drinks risky)	154	39.2%	74	37.8%	80	40.6%	0.5622

Results (all N=390 subjects, cross sectional)

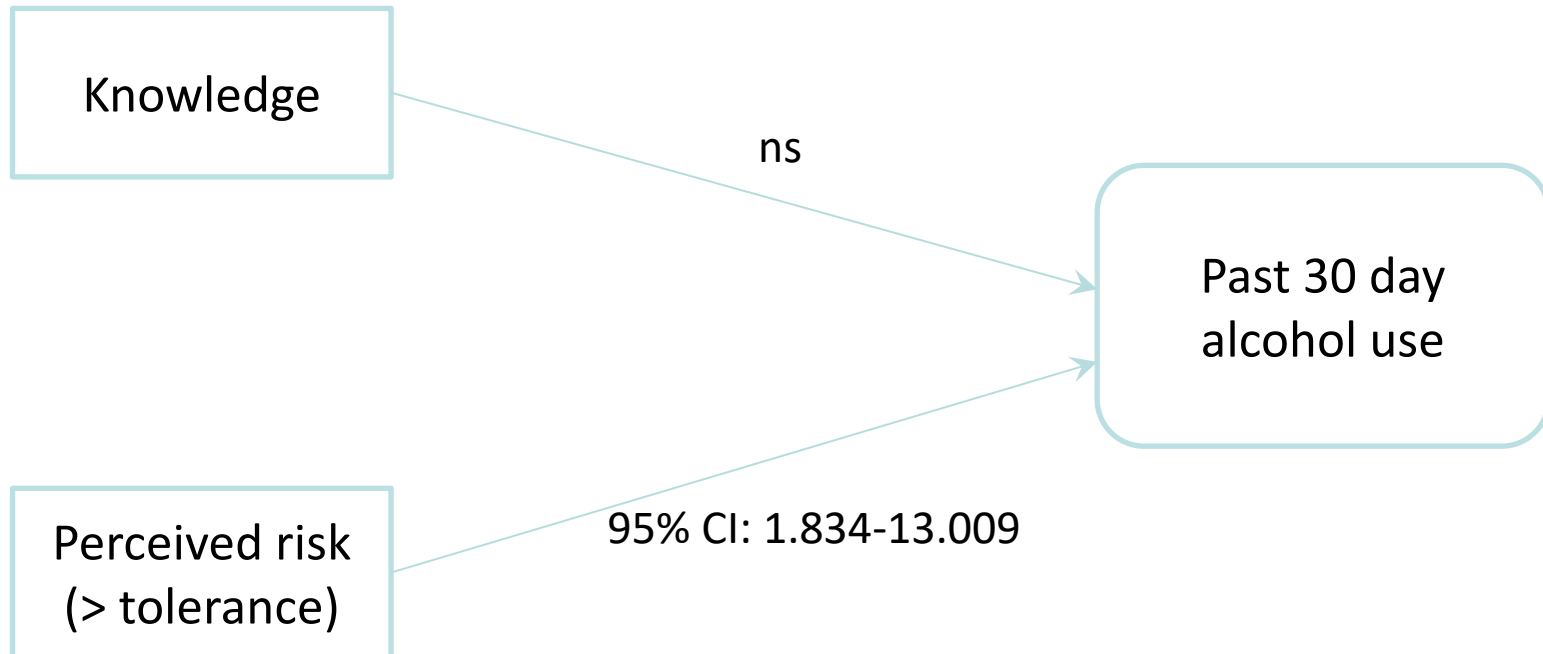
Confirmatory model – past year use, baseline*



*Logistic regression, controlling for age, gender, and race/ethnicity; ORs displayed at $p < .05$.

Results (all N=378 subjects, cross sectional)

Confirmatory model – past 30 day use, baseline*



*Logistic regression, controlling for age, gender, and race/ethnicity; ORs displayed at $p < .05$.

Changes in Alcohol Knowledge

Baseline pretest → Baseline posttest* (n=198, intervention)

- Increase in knowledge following exposure to intervention content ($p < .001$)

Baseline → 6 month follow-up* (n=224, all)

- Higher levels of knowledge compared to baseline ($p < .001$)

Baseline → 6 month follow-up by RCT group (n=224, all)**

- Above and beyond the increase in knowledge observed overall, the intervention group has additional significant bump in knowledge compared to the control group ($p < .05$)

*Wilcoxon signed-rank tests;

**GEE models with repeated observations stacked within-person

Changes in Perceived Risk

Baseline pretest → Baseline posttest* (n=195, intervention)

- Significant increase in perceived risk following exposure to intervention content ($p < .001$)

Baseline → 6 month follow-up* (n=221, all)

- No significant changes

Baseline → 6 month follow-up by RCT group* (n=221, all)

- Significant changes in perceived risk between baseline and 6 month follow-up for the intervention group, which is moving toward alcohol intolerance ($p < .05$), whereas changes were non-significant for the control group.

*Stuart-Maxwell tests of marginal homogeneity

Changes in Alcohol Use

Changes in frequency of alcohol use in the past 3 month alcohol use, baseline and 6 month (n=221, all)

- Average increase .5 day in frequency of alcohol use, unadjusted model ($p < .01$) (adjusted ns)
- No significant difference in alcohol use between control and intervention group

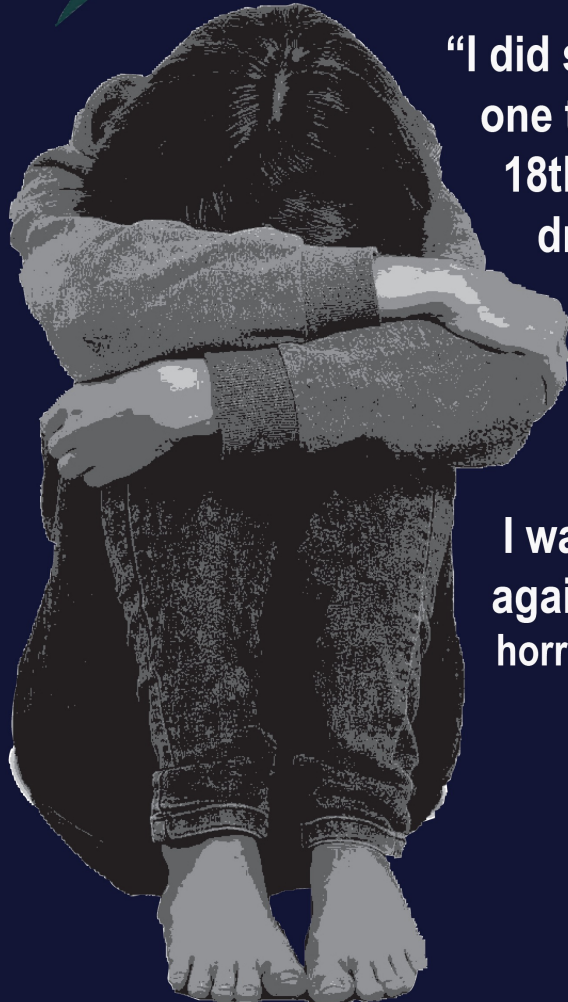
*Poisson GEE models with observations stacked within individuals; adjusted model controls for age, gender, race/ethnicity, and randomization group. An interaction term between time and the randomization group variable was used to test differences in consumption between groups.

Discussion

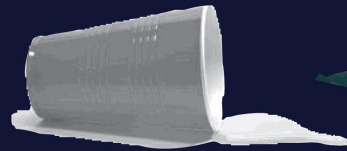
- Predicted associations hold at baseline
- Intervention impactful upon view
- Knowledge and perceived risk shifting, behavior not yet

- Project still in field – stay tuned
- Next step may be to extend to other substances...

HAPPY BIRTHDAY



“I did smoke weed one time...it was my 18th birthday and I was drunk. And...it was really bad. I got so twisted and shaking, I was cold and passing out over and over. I was so sick. I was like, “nope never again.” It was horrible.”



Acknowledgments

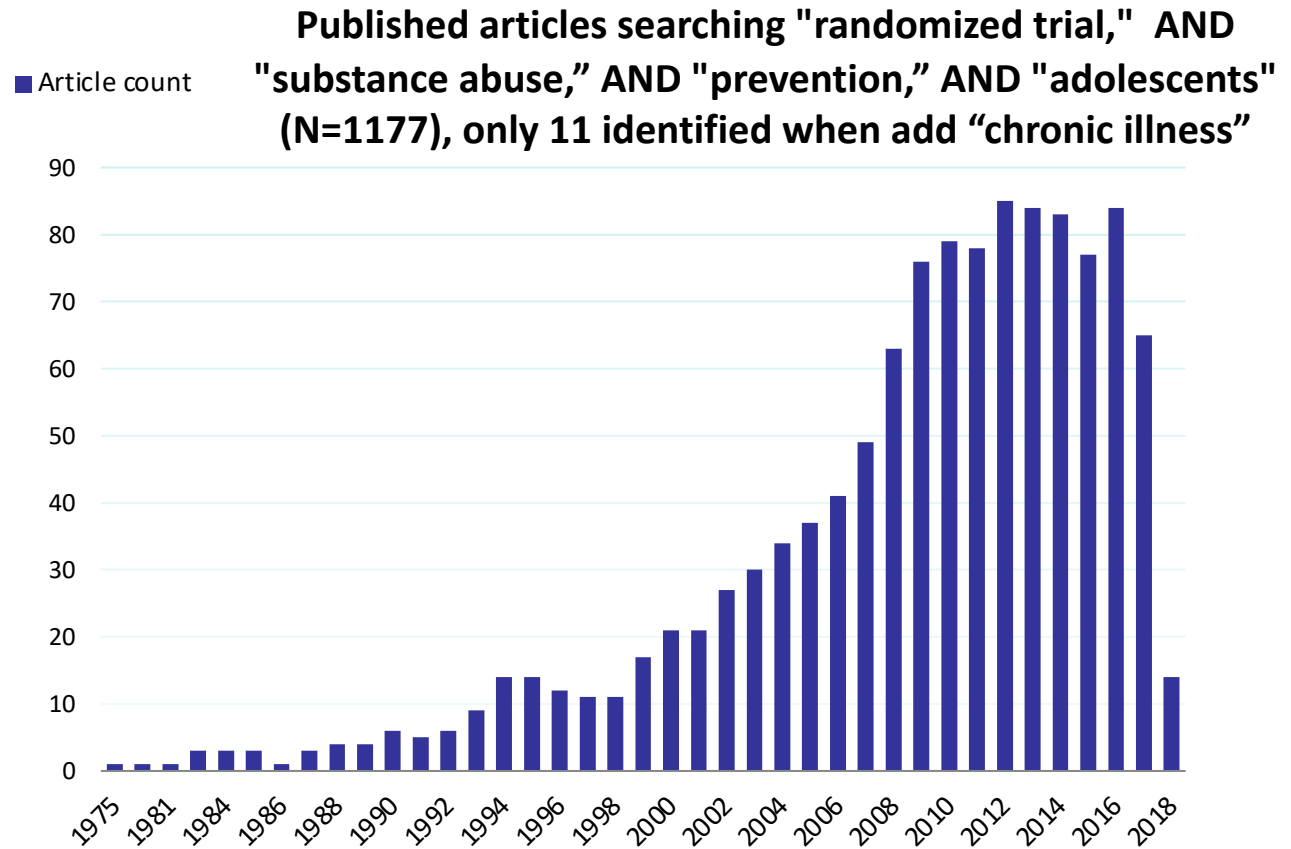
Acceptability and impacts of intervention

- Focus on pre-post, Intervention arm, baseline (n=201)

Change in perceived risk

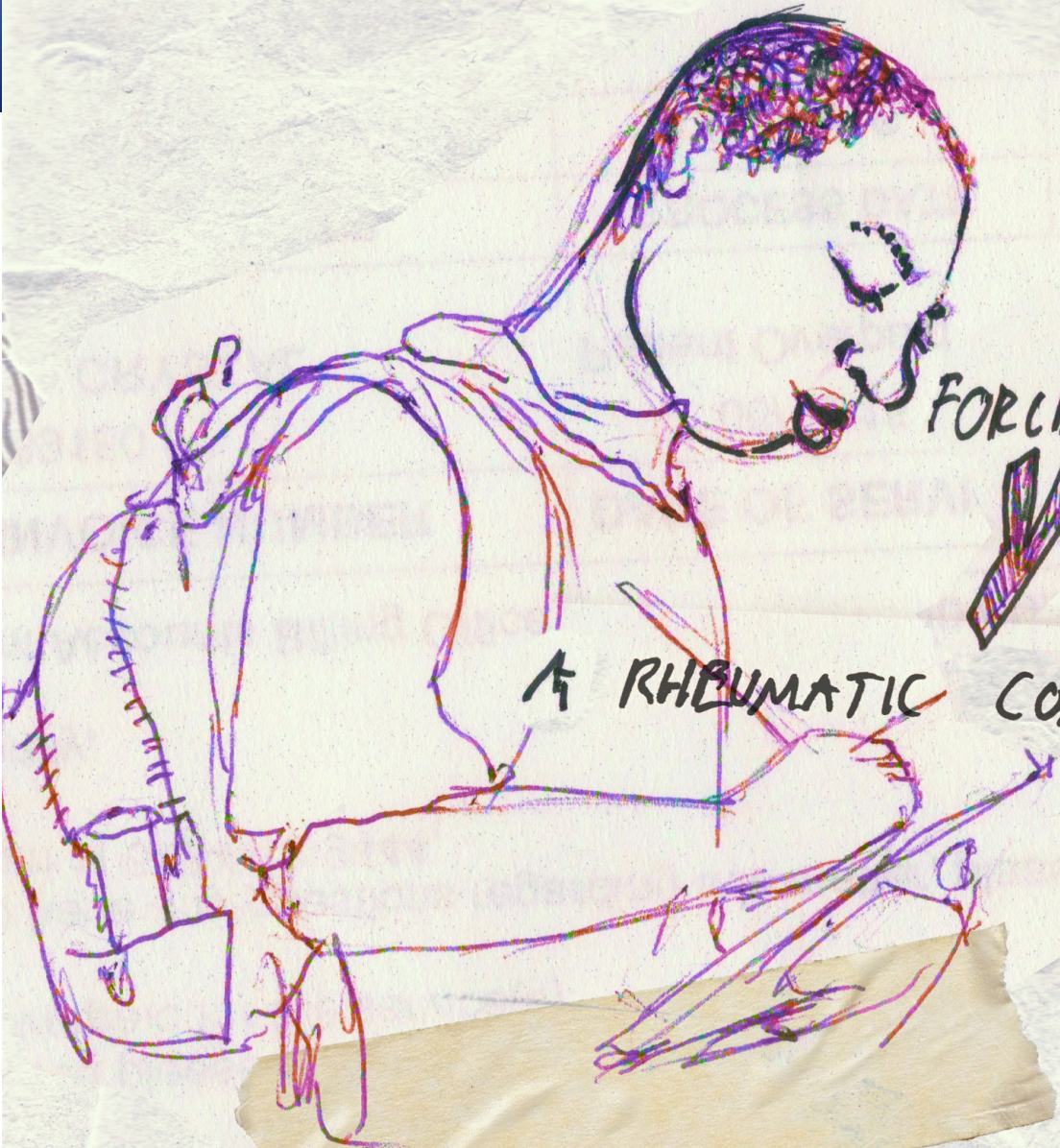
- Excel risk change figure color coded
- Blurb from slide 13 – 3rd bullet, helpful to have %s

Background



Alcohol use preventive intervention

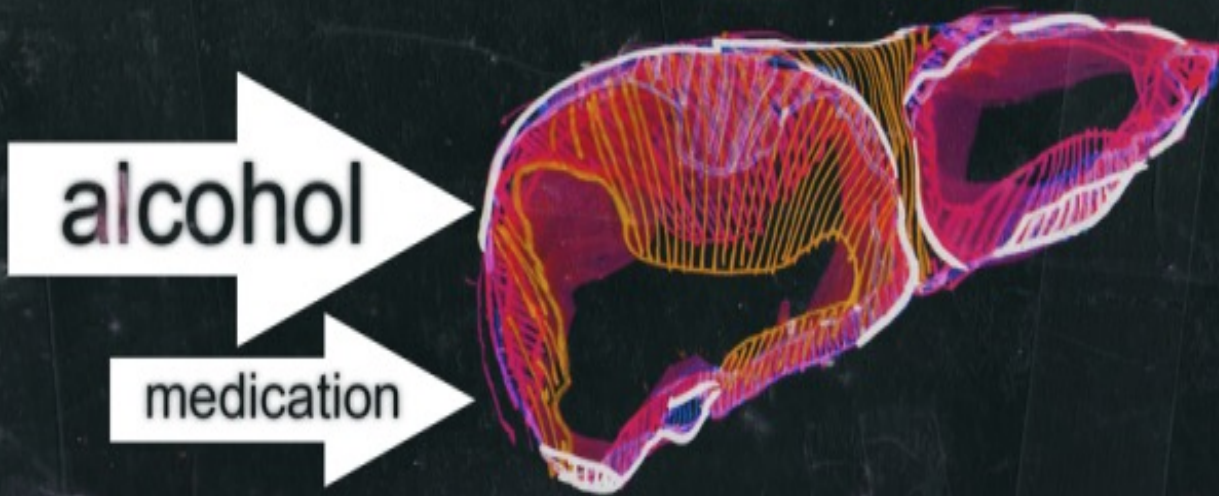
- Patient-centered, self-administered
- Dual process -- affective and factual
- Youth aesthetic
- Grounded in chronic disease frame
 - Health consequences
 - Factual mechanics of alcohol x disease
 - Addresses cognitive dissonance (adherence) & concern for toxicities
 - Plays to concern to keep symptoms and disease under control



I FEEL LIKE I WAS
FORCED TO GROW UP AT A
YOUNG AGE

A RHEUMATIC CONDITION IS KIND OF AN
ADULT THING.

Your liver works hard to process everything you put in your body, especially things like alcohol and rheumatic medications.



Your body views alcohol as a poison, and makes it a first priority to process and get rid of the alcohol.



Boston Children's Hospital
Until every child is well™

TAKE GOOD CARE



Sample demographic characteristics, aggregate and by past-year alcohol use

	Total		Past-year alcohol use				p-value
	(N=399)		Yes (N=98)		No (N=299)		
	N	%	N	%	N	%	
Age (mean, sd)	16.1	1.4	17.0	1.2	15.7	1.4	<.0001
Gender							0.4495
Male	199	49.9%	46	46.9%	153	51.3%	
Female	199	49.9%	52	53.1%	145	48.7%	
Race/ethnicity							0.0114
White non-Hispanic	324	81.2%	88	89.8%	234	78.3%	
Other race/ethnicity	75	18.8%	10	10.2%	65	21.7%	
Depression symptoms	18	4.5%	8	8.2%	10	3.4%	0.0484
Anxiety symptoms	33	8.3%	13	13.3%	20	6.7%	0.0427
Parent college degree	290	72.7%	78	79.6%	210	71.4%	0.1129
Clinic							0.3077
Endo	195	48.9%	42	42.9%	153	51.2%	
Rheum	102	25.6%	30	30.6%	72	24.1%	
GI	102	25.6%	26	26.5%	74	24.7%	
Randomization group							0.1713
Control group	198	49.6%	43	43.9%	155	51.8%	
Intervention group	201	50.4%	55	56.1%	144	48.2%	

Control and intervention groups balanced for distribution of age, gender, race/ethnicity, lifetime, past-year, and past 3 mo. alcohol use, depression and anxiety symptoms, and clinic. Intervention group higher rates of parent college (p<.01).

Intervention needs to address competing motivations of adolescents

Adolescence

- Developmental & social factors
- Resistance skills
- Impulse & drive for novelty



Health consciousness

- Awareness of physical state, vulnerability
- Value clear signals of physical state
- Concern for health consequences

Yeah, and since I have Crohn's, I never really mess with alcohol...unless [I'm at] a social event when I just happen to be in the mood for it.

Male, age 19, Crohn's disease