Protocol for the Healthy for Life Study
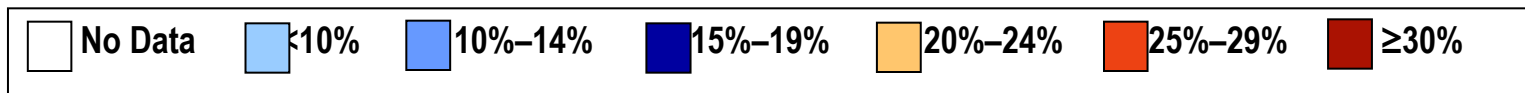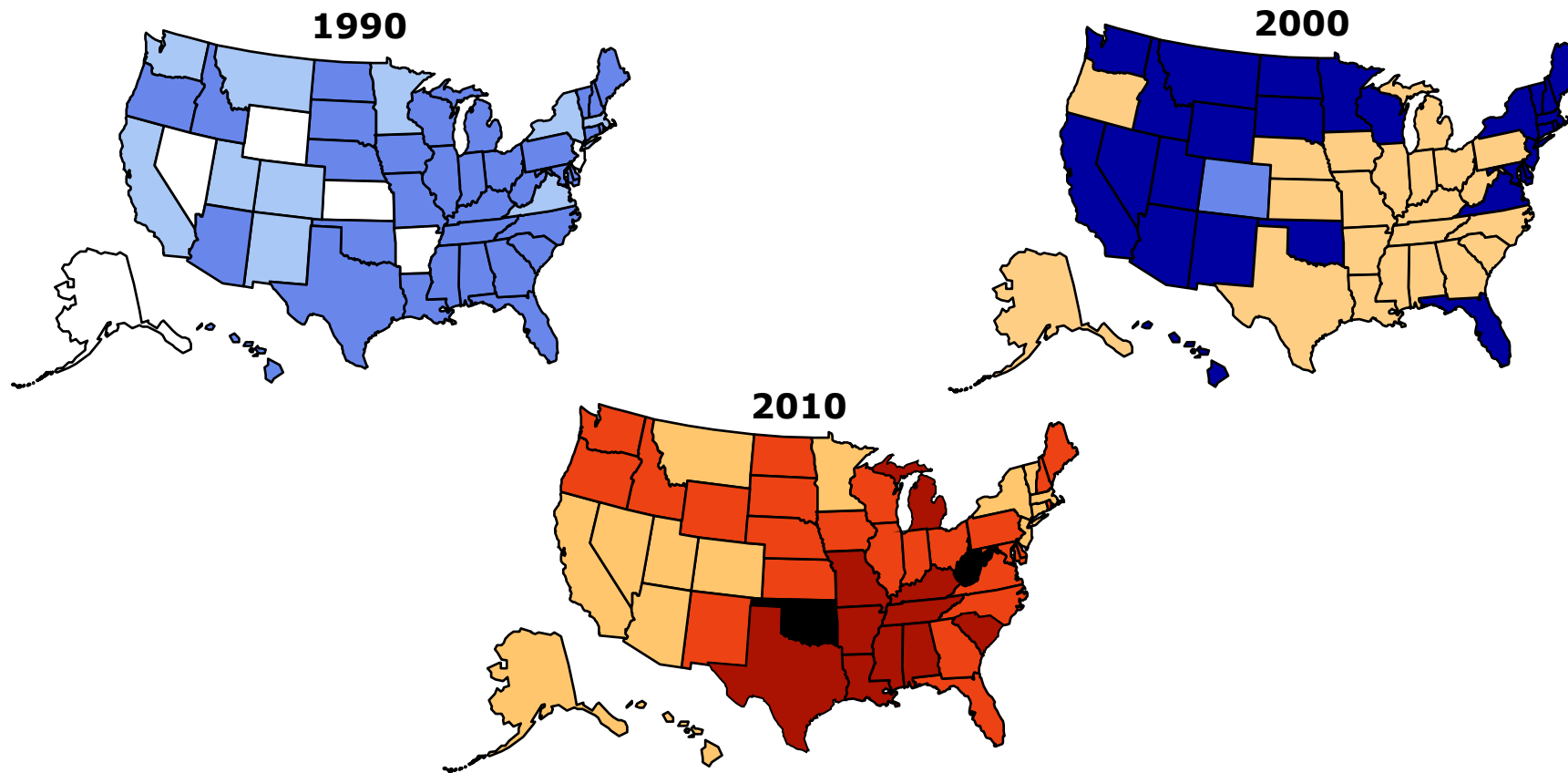
Jason Lillis, Ph.D

Disclosures

- Relevant Financial Relationships:
  - None

- Relevant Nonfinancial Relationships:
  - None

Obesity Trends* Among U.S. Adults
BRFSS, 1990, 2000, 2010

(*BMI ≥30, or about 30 lbs. overweight for 5'4" person)

1990

2000

2010

No Data	<10%	10%–14%	15%–19%	20%–24%	25%–29%	≥30%

Gold Standard Behavioral Intervention...

(Butryn, Wadden & Webb, 2011)

does not achieve long-term weight loss
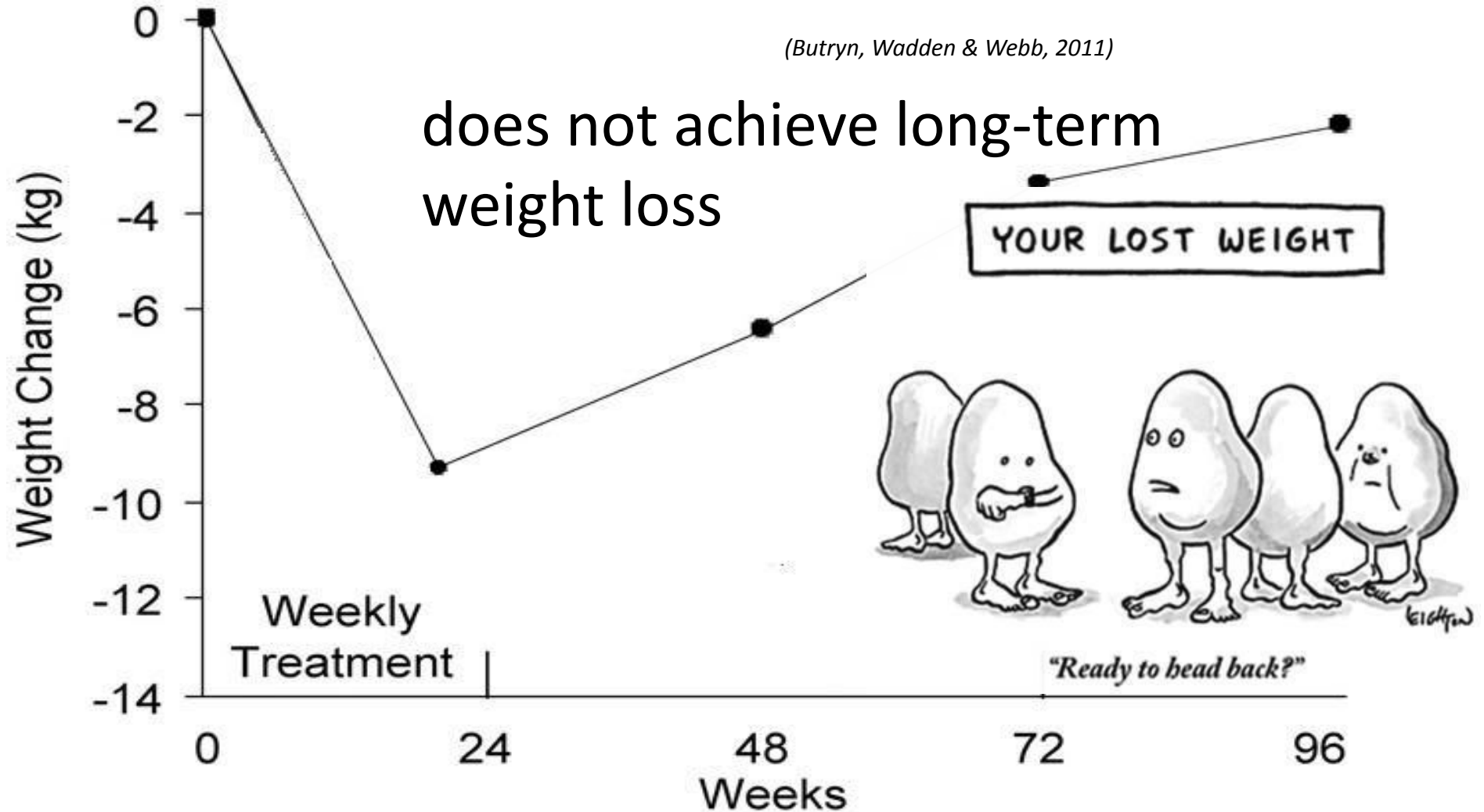
Rationale

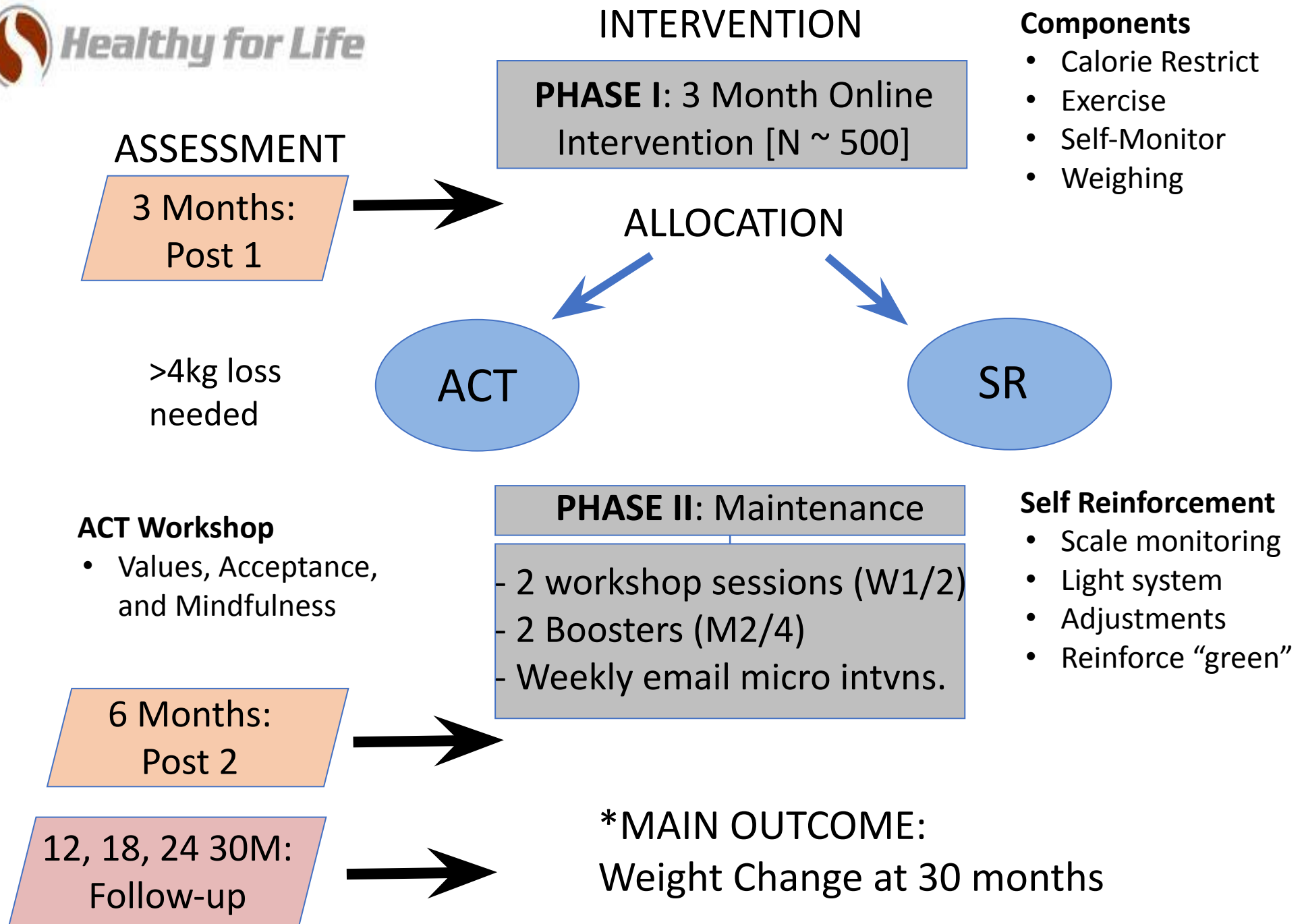- Maintenance requires "different skills"

  - Core behavior change strategies work, but individuals do not persist over time

  - Gains slow (plateau), motivation wanes, effort/burden goes up

- ACT positioned well to address long-term

  - Values skills for motivation

  - Acceptance and defusion for barriers to persisting with healthy behavior change

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Project Overview

- NIDDK funded (R01) randomized trial comparing two different WLM interventions

  - ACT vs Self-Regulation (STOP Regain)

  - ACT evidence from pilot trial (K23)

  - Self-regulation previously validated in different format

- Randomization and workshops delivered after standardized weight loss phase

Healthy for Life

INTERVENTION

Components
- Calorie Restrict
- Exercise
- Self-Monitor
- Weighing

ASSESSMENT

PHASE I: 3 Month Online Intervention [N ~ 500]

3 Months: Post 1

ALLOCATION

>4kg loss needed

ACT

SR

ACT Workshop
- Values, Acceptance, and Mindfulness

PHASE II: Maintenance

- 2 workshop sessions (W1/2)
- 2 Boosters (M2/4)
- Weekly email micro intvns.

Self Reinforcement
- Scale monitoring
- Light system
- Adjustments
- Reinforce "green"

6 Months: Post 2

12, 18, 24 30M: Follow-up

*MAIN OUTCOME:
Weight Change at 30 months

Scientific Rigor

- Control for initial weight loss (validated program)

- Random assignment to maintenance groups

- Objectively measured DVs: Weight and PA

- Blind assessment

- Counterbalanced intervention delivery with adherence to treatment protocol analysis

- Investigator team with expertise/allegiance to both conditions

- Independent Safety Monitor oversight

Progress to date

- N = 436 Phase I participants to date (excludes cohort 7)

  - 6 of 7 cohorts completed weight loss program (Phase I)

- N = 190 Phase II participants to date (excludes cohort 7)

  - 5 of 7 cohorts completed WLM programs (Phase II)

Assessment Attendance

Interval	ACT		SR		Total	
	N	%	N	%	N	%
6-12M	95	97	96	93	191	95
18-24M	11	92	15	100	26	96

Session Attendance

Session	ACT		SR		Total	
	N (93)	%	N (97)	%	N (190)	%
1	93	100	97	100	190	100
2	90	97	93	96	183	96
3	86	92	89	92	175	92
4	73	89	76	88	149	89

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Main Outcomes

- Investigators remain blind to all outcomes until all data collected

- 2 years of data collection remain

Challenges

- First cohort launched when COVID hit

  - In-person vs virtual

  - Reduced progression to Phase II

  - Recruitment woes

END

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- Rena Wing

- J. Graham Thomas

- Jessica Unick

- Erica Robichaud

- Shira Dunsiger