

# Plenary Speaker



**Bonnie Spring, PhD**



Bonnie Spring, PhD  
Director, Institute for Public Health and Medicine -  
Center for Behavior & Health  
Professor, Preventive Medicine  
Program Co-Leader Cancer Prevention

## Digital Transformation of Trials and Treatments: It's Not (All) About the Technology





## Disclosures

- Scientific Advisory Board: Actigraph
- Grant Funding: NIH

---

**22** Scientific American, October 2019

---



# A Ticking Cancer Time Bomb

Malignancies are on the rise in the most obese generation in history

*By Claudia Wallis*

## Emerging cancer trends among young adults in the USA: analysis of a population-based cancer registry




*Hyuna Sung, Rebecca L Siegel, Philip S Rosenberg, Ahmedin Jemal*



**Findings** From 1995 to 2014 there were 14 672 409 incident cases for 30 types of cancer. Incidence significantly increased for six of 12 obesity-related cancers (multiple myeloma, colorectal, uterine corpus, gallbladder, kidney, and pancreatic cancer) in young adults (25–49 years) with steeper rises in successively younger generations. Annual

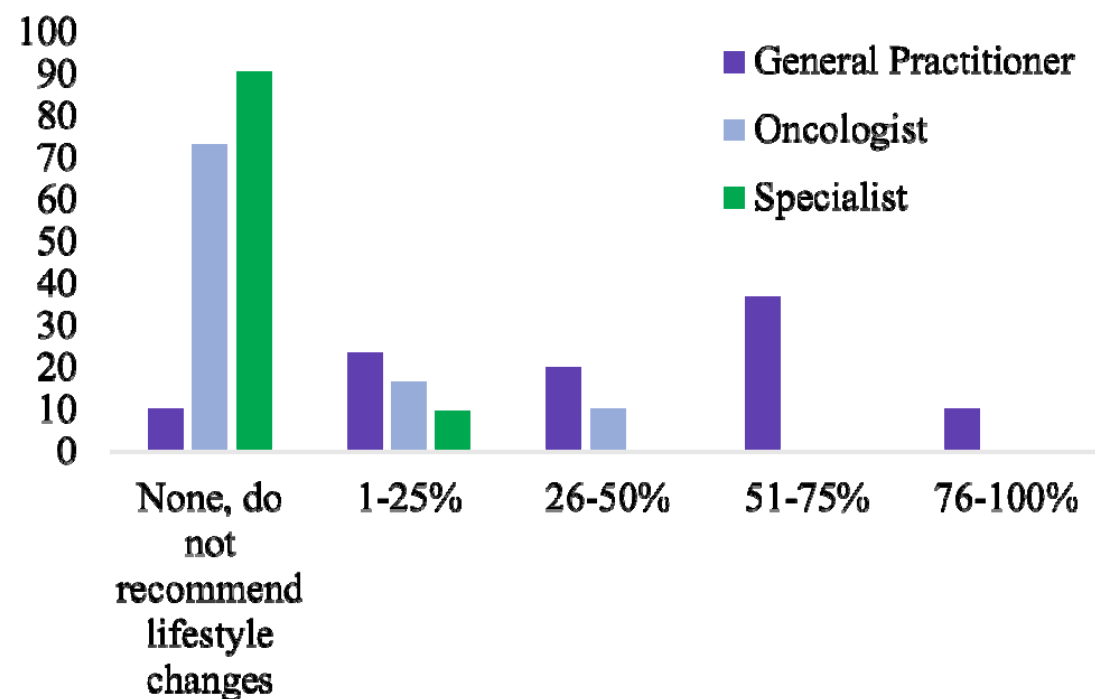
**Interpretation** The risk of developing an obesity-related cancer seems to be increasing in a stepwise manner in successively younger birth cohorts in the USA. Further studies are needed to elucidate exposures responsible for these emerging trends, including excess bodyweight and other risk factors.

## Physicians' perspectives on medication adherence and health promotion among cancer survivors

Tammy K. Stump PhD , June K. Robinson MD, Betina Yanez PhD, Frank Penedo PhD, Adaeze Ezeofor BS, Sheetal Kircher MD, Bonnie Spring PhD

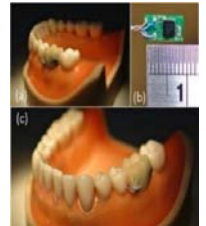
First published: 26 August 2019 |


For what percent of cancer survivors do you recommend ways of improving their lifestyle, such as smoking cessation, weight loss, or increasing physical activity?





# Abundant new sensors, apps, and devices





>97,000 apps for health and fitness;  
1000s for weight loss  
25% U.S. adults using a wearable health tracker



**What is the evidence that  
these work?**





# What do I mean by evidence?

- **Computer Scientist/Designer:** functionality, few bugs, user satisfaction, sustained use (ideally tech addiction)
- **Insurer, Hospital:** operability, privacy, security
- **Venture capitalist, Corporation:** sales, return on investment
- **Health Professional, Scientist:** accurately assesses a health outcome or efficacy/effectiveness of mHealth intervention, i.e., changes behavior, produces health outcome in research design with high internal validity (allowing causal inference), e.g., RCT or at least single case experimental designs, interrupted time series

# Evidence for what? What are we trying to accomplish?



## Objectively Assess an Outcome

### •Verification:

- Sensor measure physical construct accurately (acceleration, chews).
- Algorithm development: counts signifying deep sleep



### Validation:

- Concurrent relation to health construct (polysomnography, ECG, video of eating)
- Predictive relation to health event (weight gain)

## Improve Health Risk Behavior

(smoking, overeating, inactivity, nonadherence) to prevent onset, recurrence, multimorbidity or improve QOL

### •Digital Therapeutics:

- evidence-based therapeutic interventions driven by high quality software programs to prevent, manage, or treat a medical disorder or disease.





# STAT<sup>1</sup>

**A 'digital pill' for cancer patients is rolled out for the first time, in hopes of improving outcomes**

By [Rebecca Robbins](#)<sup>2</sup> [@rebeccadrobbins](#)<sup>3</sup>

January 17, 2019

Capecitabine (Xeloda)  
2 weeks on, 1 week off  
8 cycles  
6-8 pills/day

# BMJ Evidence-Based Medicine

June 2019



## Evidence synthesis: Mental health

### Digital aripiprazole or digital evergreening? A systematic review of the evidence and its dissemination in the scientific literature and in the media

Lisa Cosgrove,<sup>1</sup> Ioana Alina Cristea,<sup>2,3</sup>  
Allen F Shaughnessy,<sup>4</sup> Barbara Mintzes,<sup>5</sup> Florian Naudet<sup>6</sup>

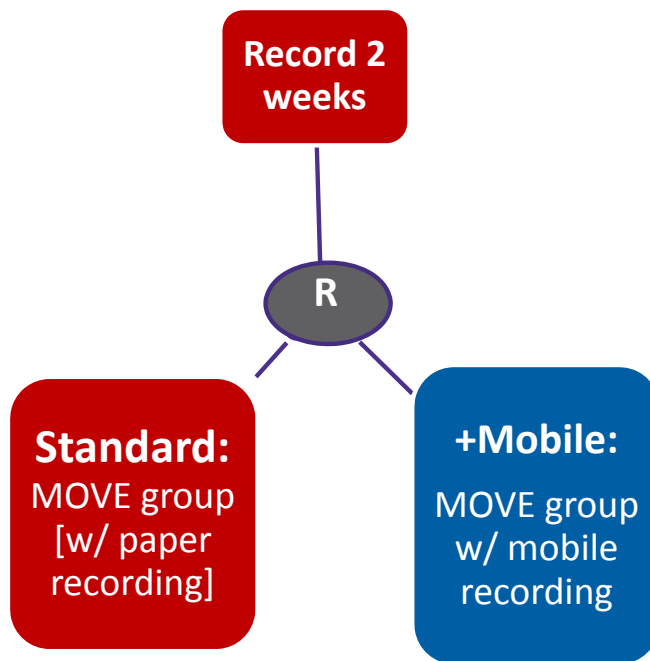
- No RCT comparing digital aripiprazole with nondigital formulation, other active comparator, or placebo.
- 14 scientific papers: no data on remission, QOL or efficacy.
  - 11/14 convey unsupported benefit
- 70 news stories
  - 52/70 convey unsupported benefit



## Prevention, Health Promotion: Mobile Health Weight Loss Programs (text, app, wearable, hybrid)

- Kaplan & Stone, *Ann Rev Psych*, 2013 - 21 mHealth RCTs;
  - 6 (29%) show mHealth > control
- Burke, Ma,..Spring, et al, AHA Behav Change Comm, *Circulation*, 2015 – 38 mHealth RCTs (weight, PA, smoking)
  - 5/8 (63%) U.S. obesity RCTs mHealth > control at some f/up
  - **SMS alone ineffective for weight loss**
- Wang, Xue, et al, *Adv. Nutrition*, 2017 - 24 studies mobile, wireless
  - >50% improve weight loss or diabetes control
- **Engagement/maintenance challenging**

## +Mobile Study (all new referrals to VA MOVE!)



**Table. Demographic Characteristics of the Study Participants at Randomization<sup>a</sup>**

| Characteristic            | Connective<br>Mobile<br>Group<br>(n = 34) | Standard<br>Group<br>(n = 35) | Total<br>(N = 69) |
|---------------------------|---|-------------------------------|-------------------|
| Age, mean (SD), y         | 57.7 (13.5)                               | 57.7 (10.2)                   | 57.7 (11.9)       |
| Male sex                  | 29 (42.0)                                 | 30 (43.4)                     | 59 (85.5)         |
| Ethnicity                 |   |                               |                   |
| Hispanic or Latino        | 1 (2.9)                                   | 3 (8.6)                       | 4 (5.8)           |
| Not Hispanic or Latino    | 33 (97.1)                                 | 32 (91.4)                     | 65 (94.2)         |
| Race                      |   |                               |                   |
| White                     | 25 (73.5)                                 | 27 (77.1)                     | 52 (75.4)         |
| Black or African American | 9 (26.5)                                  | 8 (22.9)                      | 17 (24.6)         |
| College graduate          | 10 (29.4)                                 | 14 (40.0)                     | 26 (37.7)         |
| Anthropometry, mean (SD)  |   |                               |                   |
| Weight, kg                | 113.7 (16.1)                              | 110.1 (15.1)                  | 111.1 (15.6)      |
| BMI                       | 36.9 (5.4)                                | 35.8 (3.8)                    | 36.3 (4.6)        |
| Waist circumference, cm   | 120.4 (14.0)                              | 120.4 (8.9)                   | 120.4 (11.7)      |

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

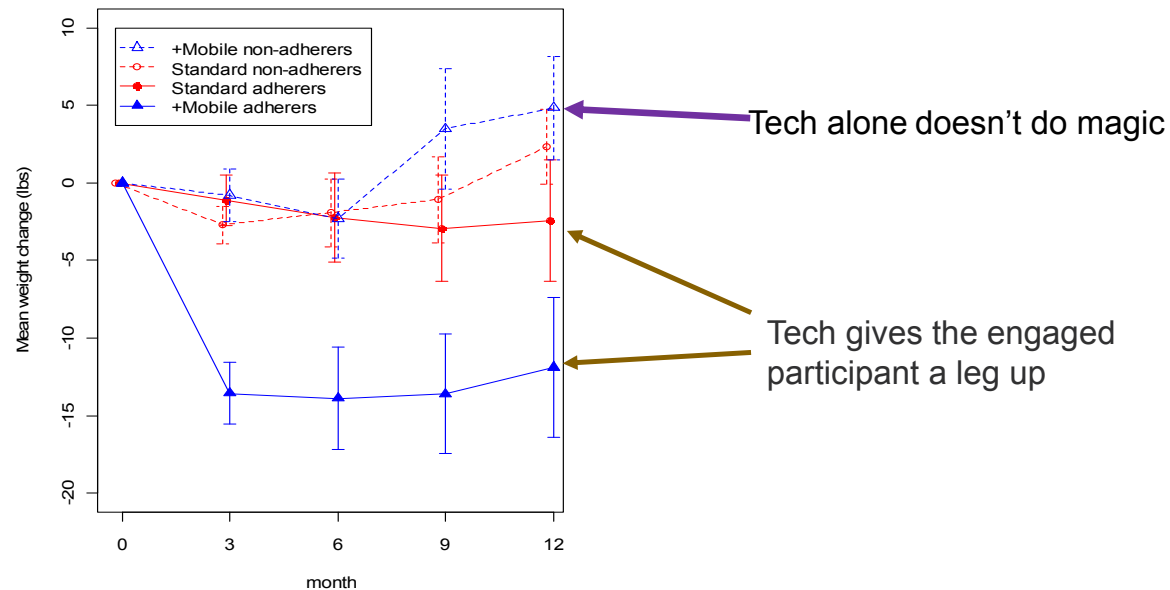
<sup>a</sup>Data are presented as number (percentage) of study participants unless otherwise indicated. No between-group differences in baseline variables were observed.

*Spring et al, JAMA Int Med,*  
2013, 173(2):105-111



## Weight loss over time as a function of mHealth technology access and group treatment attendance \*

\* Adherent =  
Attended  
≥80% of  
treatment  
sessions.



Spring et al, *JAMA Int Med*, 2013, 173(2):105-111

## Same intervention or different?

HL075451



DK108678

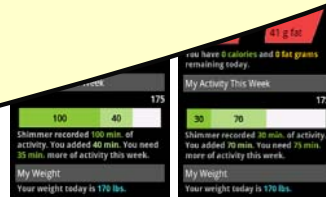


Techniques

• Goal setting

Tech changes rapidly, but **it's not the widget that's doing the work. Human behavior change principles are the agent, and they remain the same (or evolve very, very slowly.)**

Accountability

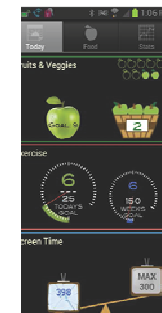


DK087126

DK097364



HL075451



# RANDOMIZED TRIAL OF TEXT-MESSAGING TO REDUCE EARLY DISCONTINUATION OF ADJUVANT AROMATASE INHIBITOR THERAPY IN WOMEN WITH EARLY STAGE BREAST CANCER: SWOG S1105

Dawn L. Hershman, Joseph M. Unger, Grace Clarke Hillyer, Anna Moseley, Kathryn B. Arnold, Shaker R. Dakhil, Benjamin T. Esparaz, Ming C. Kuan, Mark L. Graham, II, Douglas M. Lackowski, William J. Edenfield, Zoneddy R. Dayao, Julie R. Gralow, Scott D. Ramsey, Alfred I. Neugut

# CONCLUSION

- Simple bi-weekly unidirectional text messaging did not result in improved adherence based on the primary or secondary endpoints
- Passive text messaging may be insufficient due to electronic information overload
- Improving long-term adherence may require enhanced provider-patient communication, personalized sustained behavioral interventions, symptom management and support
- **AKA Support and Accountability**



# Practical Advice to Motivate Healthy Behavior Change

- Assess, Advise, Agree, **Assist**, Arrange

## Help patients find apps/technologies that

- Were evaluated in RCTs (or sound alternative design (single case experimental, stepped wedge, multiple baseline))
- Incorporate evidence-based behavior change principles: goal setting, self-monitoring, feedback, social support/accountability



# Thank you!



- NIH
  - R01DK108678 (Spring)
  - R01DK097364 (Spring)
  - T32CA193193 (Spring)
- AHA
  - 14SFRN20740001 (Spring)
- NIH
  - NCI RLCCC (Platanias)
  - U54EB020404 (Kumar)
  - UL1TR001422 (Lloyd-Jones)



**Back row (L to R):** Angela Pfammatter, PhD; Alexa Mitsos; Philip Rak, MBA; Sean Arca; Gene McFadden; Bonnie Spring, PhD, ABPP; Laura Martindale; Shirlene Wang; Ekaterina Klyachko, PhD; Gleb Iakovlev; Susan Hood, PhD  
**Front row (L to R):** Sara Hoffman, MS; Alejandra Povedano; Elyse Daly; Sasha Cukier; Margaret DeZelar; Hannah Rumsey; Tammy Stump, PhD; JC Subida