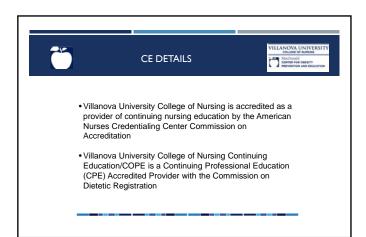


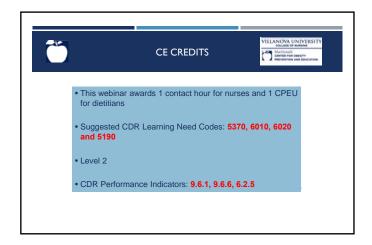


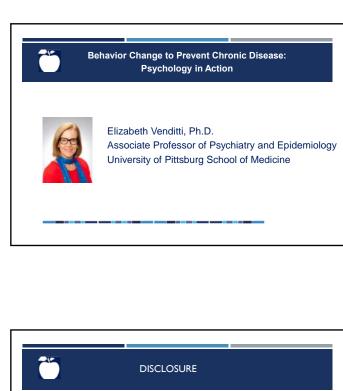


OBJECTIVES

- Discuss key components of evidence-based lifestyle interventions
- Describe the efficacy trials and translational research contributing to current public health science (specifically related to obesity management/diabetes prevention) in high risk groups
- Identify challenges that remain in the field to improve translational and public health







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Behavior Change to Prevent Chronic Disease: Psychology in Action

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Outline for Today's Presentation

Rationale for behavior change interventions in obesity/diabetes prevention for adults (why)

Fundamental intervention components (what)

Evidence base from some major randomized trials and translational effectiveness studies

Implications for integrated clinical practice

Type 2 Diabetes in the US

- > 30 million with diagnosed diabetes (~ 10 % of US population)
- ~ 84 million with "pre-diabetes" (most don't know)
- 1 out of 3 people will develop diabetes in their lifetime
- Prevalent in Blacks, Hispanics, American Indian, Alaska Native, Native Hawaiian/Pacific Islanders

Source: American Diabetes Association 2018



Diabetes is Costly

- Driving force is Type 2 diabetes (accounts for 90-95% of all diabetes cases)
- Estimated that \$1 out of \$7 total health care dollars is spent treating diabetes and its complications
- Total costs--\$327 billion and rising

Source: American Diabetes Association 2018

Rationale: Why Bother With Lifestyle Behavior Change?

- •We know genetic, physiologic, psychosocial factors are complex and we need to address individual vulnerabilities
- Yet...food/activity environment is potent in shaping habits in animals and people ("a final common pathway")
- •The bargain: lifestyle interventions impact energy balance behavior change and influence broad spectrum physical outcomes, health related quality of life and well-being, depression



Lifestyle Self-Management is Good Medicine

- Person, environment and cognition interact to shape healthy behavior and counter unhealthy behavior
- Primary focus is on building capacity to selfregulate in changing (sometimes toxic) environments
- Emphasis is on social learning (thinking/behavior), social norms, social support and social ecology ("taking charge of what's around you")

Bandura, A. Health promotion by social cognitive means (2004) Health Education and Behavior: 31, 143-164.

If lifestyle intervention is good medicine, what is a minimally effective dose?

- 1-8: Self-management of diet/nutrition, physical activity, weight, environment
 - (specifies weight, activity, calorie/fat goals, self monitoring for induction of weight loss, core behavioral skills)
- 9-16 and beyond: Psychological and behavioral skills; trial and error problem solving and application re: personal barriers for healthy eating and activity

Multicomponent lifestyle interventions Commit to program Set goals Set goal

Diabetes Prevention Program (DPP)
Intensive Lifestyle Intervention as an exemplar
(many came before...innovations since)

- Goal based (7% weight loss; 150 minutes per week moderately vigorous physical activity)
- Individual case managers or "lifestyle coaches" or group leaders to facilitate basic selfmanagement/problem solving skills
- Structured "core curriculum" sequence; flexibility to adapt within standardized format (gold-standard is 16 sessions over 6 months)
- Less frequent, but regular contact following core program delivery (e.g. monthly contacts)

DPP Maintenance Intervention

- Required in-person contact at least every two months
- Interim phone/mail contact
- DPP delivered 50.3 (±21.8) total sessions over 2.8 years
- Supplemental group classes
- Motivational "campaigns", "boosters", "restarts"

Lifestyle Intervention Evidence (Adults)



Long history of obesity outcomes research shows weight loss is feasible, achievable

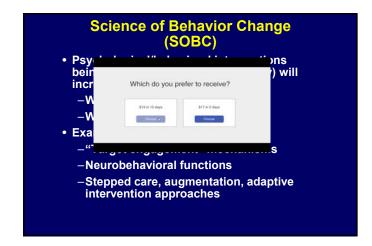
Randomized-controlled behavioral treatment studies (since 1970's)* show it's possible to achieve (on average)

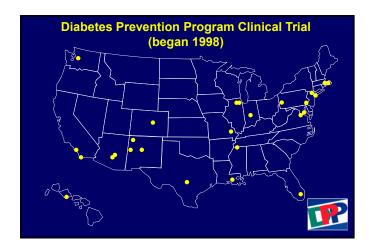
- 10% loss at ~ 6 months (e.g. ~ 10 kg in 200 lb individual)
- Longer duration contact = better weight loss
- Regain is the norm; maintenance contacts and moderate- high levels of physical activity slow rate of regain
- Many multi-site RCT's show 4-8% average weight loss at ~ 1-3 years (~ 5 kg)

Wadden TA (multiple reviews listed in PubMed)

But what about non-responders?

- More of the same is not better. There are "late bloomers" but not as likely.
- The first two months of behavioral lifestyle intervention often predicts long term response
- Unick et. al (2014) showed achieving ≥ 2% loss at 8 weeks predicts likelihood of 10% weight loss at one year
- Only 15% of those who don't show this marker of weight loss response go on to succeed at that level.





DPP Primary Intervention Goal

 To prevent or delay the development of type 2 diabetes in persons with impaired glucose tolerance (IGT)

Feasibility of Preventing Type 2 Diabetes

- Long period of glucose intolerance that precedes the development of diabetes
- · Screening tests identify persons at higher risk
- Safe, potentially effective interventions can address modifiable risk factors

Modifiable	Risk Factors	s for
Type	2 Diabetes	

- Obesity
- Body fat distribution
- Physical inactivity
- Rising fasting and 2 hr glucose levels

DPP Study Design

- 3-group RCT (lifestyle, metformin, placebo)
- 27 clinical sites
- Standardized across clinics:
 - -Common protocol and procedures manual
 - -Expert staff training
 - -Data quality control program

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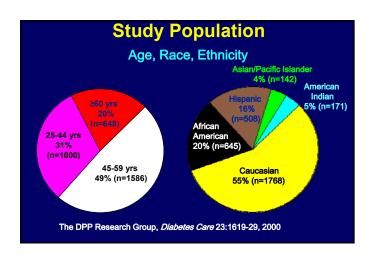
DPP Eligibility

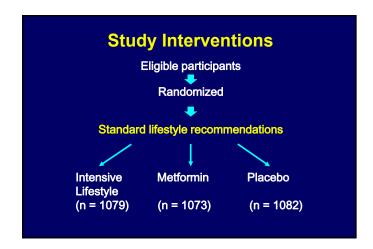
- Age ≥ 25 years
- Elevated plasma glucose
 - -2 hour glucose 140-199 mg/dl and/or

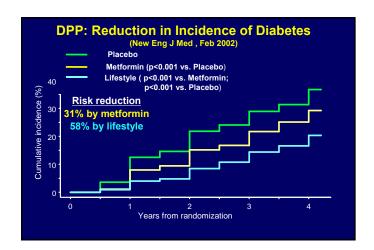


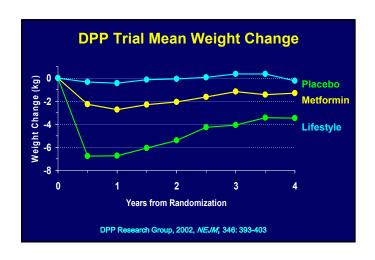
- -Fasting glucose 95-125 mg/dl
- BMI > 24 kg/m² (Asian-American/22 kg/m²)
- Goal: recruit at least 50% of sample from high risk race/ethnic groups

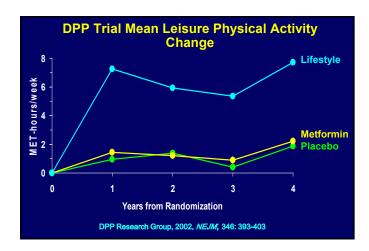
Screening and Recruitment Number of participants Step 1 screening 158,177 Step 2 OGTT 30,985 Step 3 start run-in 4,719 Step 3 end run-in 4,080 Step 4 randomization 3,819* *3,234 in 3 arm study (585 in troglitazone arm) DPP Research Group, Controlled Clin Trials (2002)

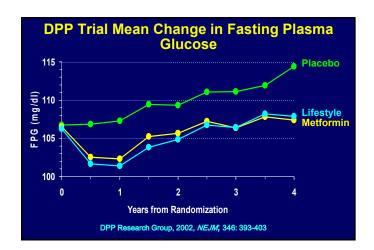












DPP: Weight loss was the dominant determinant of reduced diabetes risk

- Each kg of weight loss associated with 16% reduction in diabetes risk
- Lower % calories from fat predicted weight loss
- Increased physical activity predicted weight loss maintenance over time
- was independently associated with decreased diabetes risk (among those not at 7% weight loss goal)

Hamman et al, Diab Care 29: 2102-2107, 2006



DPP Calorie and Fat Changes 0-12 months

- Mean kilocalories
 Decreased 450/day
 (from 2137 to 1687)
- Mean percent calories from fat Decreased 6.6% (from 34.1% to 27.5%)

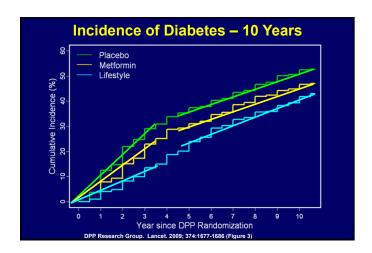


Hamman et al, *Diab Care* 29: 2102–2107, 2006

DPP > Bridge Period > DPPOS

- 2001 2002
 - Completed individual treatments
 - Metformin wash-out (4-8 weeks)
- January June 2002
 - <u>All</u> participants offered 16-session group DPP program over six months
- September 2002-present
 - DPP "Outcomes Study" (offered some lifestyle intervention to all, up to 20% attended)

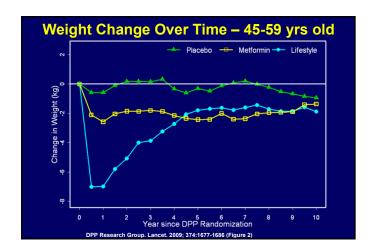
Weight Change Over Time – 10 Year Data Placebo Metformin Lifestyle Placebo Metformin Lifestyle Placebo Metformin Depresser Since Depression Street Depression Depression Street Stree



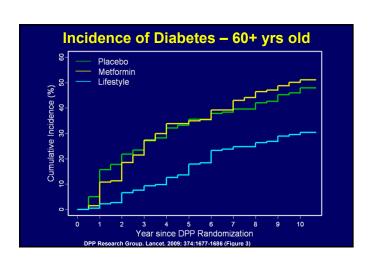
Cardiovascular Risk Reduction

- All groups (lifestyle, metformin, placebo) had decreased blood pressure, cholesterol and triglycerides.
- Lifestyle participants had same or lower blood pressure and lipid levels over time than other participants with less use of medicines.









15-years of follow-up and counting... (we continue to learn) Long-term effects of lifestyle intervention or metformin on diabetes development and microvascular complications over 15-year follow-up: the Diabetes Prevention Program **Outcomes Study** Description Background Effective prevention is needed to combat the worldwide epidemic of type 2 diabetes. We investigated the long-term extent of beneficial effects of lifestyle intervention and mediornin on diabetes prevention, originally shows during the 3-year Diabetes Prevention Program (DPP), and assessed whether these interventions reduced diabetes associated microscolards complications.

Efforts to translate the DPP lifestyle program are expanding rapidly

- YMCA-DPP
- **National DPP-Prevent** T2D
- Indian Health Service
- State Health Depts
- VAMC-MOVE
- Faith-based
- Primary care, worksite, military)

Reimbursement available

- **CMS/Medicare** (classroom-based)
- **United Health Care** (other payers)

Now being evaluated

- · Medicaid models
- Web-based coaching

NDPP Results (Feb 2012-Jan 2016) Ely et al, Diabetes Care (Oct 2017)

METHOD:

Studied N = 14, 747 men and women (18+ years) enrolled in year-long program. Session schedule:

- -16 in first six months
- 6 in last six months

RESULTS

- Median attendance = 14 sessions
- Median days in program = 134 (~ 19 weeks)
- Average weight loss = 4.2% (median = 3.1%)
- 35% achieved 5% weight loss goal
- · 41.8% achieved 150 min/per week goal

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Pitt Retiree Study: Group Lifestyle Balance (GLB) (2012-2018)

- 322 adults (65-80)
- 12 sessions, in person
- At 4-months from baseline:
 - -Group Phone Calls (8 sessions, 8 months)
 - -Newsletter Control
- Primary outcome = weight change at 12-months

Community Based Screening

Targeted "high-yield" settings for participants in the target age and risk range (BMI ≥ 27 plus 1 additional cardiometabolic risk factor)

- Pitt Retirees (via Benefits Office)
- Pitt Claude Pepper Registry
- Pitt Clinical and Translational Science Institute
- Hospital Community Outreach Foundation
- Pennsylvania Public School Employees Association-Retired (PSEA-R)
- Senior Services organizations and centers

Month 12 Results

(paper in process)

Weight loss (primary outcome)

- Phone group: -7.5% (5.5)
- Newsletter group: 5.8% (6.1)
- Between group P = 0.01

Secondary outcomes (physical activity, physical function, lipids, waist, blood pressure)

- Phone group: slightly more favorable consistent with degree of weight loss (between group P = ns)
- Both groups showed modest physical and mental health-related quality of life benefits

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So is lifestyle self-management good medicine? THE MIND-BODY PROBLEM No.

Pitt Retirees with mild depressive symptoms show benefit					
	MDS Present 24% (n = 45)		MDS Absent 76% (n = 141)		
Measure	Baseline Mean (sd) or Median [IQR*]	4 mos Δ Mean (sd) or Median [IQR*] p-value	Baseline Mean (sd) or Median [IQR*]	4 mos Δ Mean (sd) or Median [IQR*] p-value	Between Group Δ p-value
BMI (kg/m²)	33.7 (5.0)	-2.1 (1.2) <.0001	33.0 (4.6)	-2.2 (1.1) p <.0001	0.77
Weight (lb)	192.4 (25.8)	-12.3 (7.3) <.0001	199.7 (36.2)	-13.1 (6.7) p <.0001	0.46
Percent Weight Change		-6.4 (3.7) <.0001		-6.6 (3.1) <.0001	0.74
SF-12 PCS	45.7 (7.7)	(3.5 (5.6) <.0001	49.6 (7.8)	+1.1 (7.2) p <.01	<0.02
SF-12 MCS	50.6 (8.9)	-0.6 (8.4) 0.44	57.1 (4.9)	-0.3 (5.5) 0.68	0.79
CES-D	14 12,17	2 [7,+2]	4 2,7	0 [1,+2] 0.16	0.003

Implications for integrated clinical practice

Mind/body health is just "health"

- Manualized (scalable) evidence-based interventions are the foundation
- Adaptive or stepped care intervention is needed for non-responders
- Teams of multi-disciplinary professionals (mind and body experts) and support staff play a critical role in delivery

Thanks for listening. Questions/discussion vendittiem@upmc.edu (412) 647-1027

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