Comparative Effectiveness of Diabetes Prevention Programs

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Diabetes and Pre-Diabetes

- 20.8M people have diabetes in US; 95% Type 2
- Estimated 54M people have pre-diabetes
- 61% of Monroe County adults are overweight or obese
- Estimated 20% of MC adults are pre-diabetic
- Rate of diabetes in MC doubled from 2001-2006
- 20% of African Americans in Rochester have DM compared to 10% of MC population overall, and 39% (vs. 24%) are obese

Costs of Diabetes

- $58B in reduced national productivity
- $116B in excess medical expenditures
- An average expenditure of $6,649 more/year than non-diabetics (230% more)

What We Know:
What Does NOT Work

- Brief interventions

  Goldstein, Whitlock, & DePue (2004)

- Web-based interventions

  Verheijden et al. (2004)

- Interventions in primary care

  Yarnell, Pollak, Ostbye, Krause, & Michener (2003)

What DOES Work?

- Evidence based programs developed and studied in research settings
- Require translation to clinical and community settings
- Diabetes Prevention Program

Comparative effectiveness of practice-based diabetes prevention programs

The Diabetes Prevention Program

Program

For first 6 months:

- 3 Group mtgs./month
- 1 individual mtg./month
- Providers: Nutritionist, physical activity counselor, PA

For following 6 months:

- 2 Group mtgs./month

Effectiveness

- Delayed diabetes onset by average of 11 years
- Required 5-10% weight loss and increased PA to 150 mins/wk
- Reduced relative incidence of diabetes by 58%
- Cost effective in a research setting

Healthy Living Program

- Program
  - Groups held in community sites
  - 1.5 hours 2 X /week
  - Physical activity – 45 minutes
  - Comprehensive health promotion curriculum
  - Not focused on weight loss in original program
- Effectiveness
  - Average wt loss = 3 lbs.
  - Small % achieved 5-7% loss
  - Average waist and hip significantly decreased
  - Significant increase in PA
  - Significant increase in vegetables consumed
  - Significant decrease in fats and salt

Comparative Effectiveness of Diabetes Prevention Programs: CTSI Pilot

- Trial of two interventions to increase physical activity and decrease weight among pre-diabetics, to prevent diabetes among patients served by community health centers
- Translation of research program (DPP) to clinical setting, and comparison to another program (HLP) specifically developed for African American and Latino populations

Specific Aims

- To test the feasibility of recruitment and randomization of low income pre-diabetics in primary care offices.
- To test the feasibility of collecting measures of weight, physical activity, behavior, and motivation.
- To collect robust preliminary data to determine effect direction and size for an R21 or R01.

Design

- Pre-diabetic patients in four community health centers
- Randomized trial – DPP vs HLP
- Recruitment goal – 50 per site recruited with 25 randomized to each arm in each site
- Expected 40% attrition rate

Inclusion Criteria

- Adults (18 years or older) who are overweight or obese (BMI $\geq$ 25 kg/m^2)
- Pre-diabetes (tested within the previous 12 months), as defined by the ADA:
  - Hemoglobin A1C 5.7 – 6.4%
  - Fasting plasma glucose 100-125 mg/dl
  - Oral glucose tolerance test 140-199 mg/dl
- Able to participate – Physical Activity Readiness Questionnaire (PAR-Q)

Exclusion Criteria

- Diabetes at baseline or previous use of anti-diabetic medication , other than during pregnancy
- Medical conditions likely to limit life span and/or increase risk of intervention
- Conditions or behaviors likely to affect conduct of the trial
- Medications and medical conditions likely to confound the assessment for diabetes

Interventions: HLP vs DPP

Characteristics of programs	HLP	DPP
Weeks	12	22
Sessions per week	2	1
Total sessions	24	22
Hours per week	3	1
Total hours	36	19
Total hours of counseling	18	19
Total hours of physical activity	18	0

Outcomes

- Primary outcomes:
  - percent weight loss relative to baseline
  - self-reported minutes/wk of physical activity
- Secondary outcomes:
  - BMI change
  - self-reported nutrition and physical activity
  - measures of motivation

Measurements

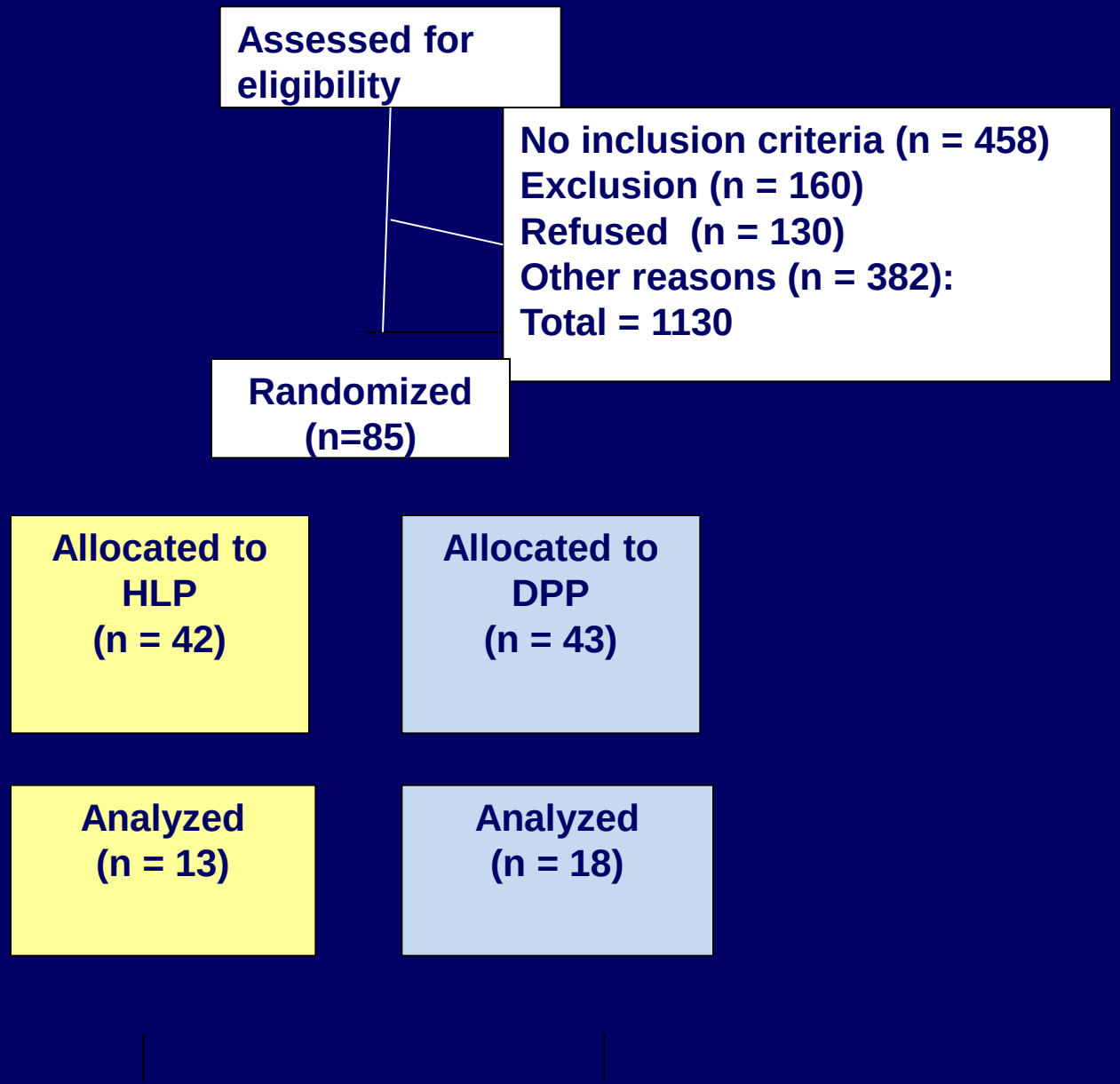
Measures	**Baseline**	**Q 4 wks**	**22 weeks**
Demographics	X		
Biometrics: ht, wt, waist, hip, BP, HR	X	X	X
Cardio-resp endurance, strength, flexibility	X	w12 only	X
Physical Activity (Self report) mins/wk	X	X	X
Nutrition (self report)	X	w12 only	X
Motivation	X	X	X
Satisfaction		X	X

Analysis

- Univariate and bivariate descriptive analyses
- Primary analysis will compare weight loss and minutes of physical activity per week - 3 way ANOVA including program, time, and clinic
- Regression as needed to model temporal change in weight loss.
- Construction of model of changes in motivation leading to behavior change – identification of factors.

Results

CONSORT diagram



Participants

Characteristics	HLP n (%)	DPP n (%)	Total n (%)
Gender			
Female	33 (78.57)	43 (86.00)	76 (82.61)
Male	9 (21.43)	7 (14.00)	16 (17.39)
Race/ethnicity			
Hispanic	5 (11.90)	6 (12.00)	11 (12.00)
Non-Hispanic White	9 (21.43)	9 (18.00)	18 (19.57)
Non-Hispanic Black	26 (61.90)	30 (60.00)	56 (60.87)
Other	2 (4.76)	5 (10.00)	7 (7.61)
Do you have insurance? (% yes)	37 (88.10)	45 (90.00)	82 (89.13)
Insurance Type			
Public (Medicaid/Medicare)	25 (59.53)	32 (64.00)	57 (61.96)
Private	12 (28.57)	13 (26.00)	25 (27.17)
None	5 (11.90)	5 (10.00)	10 (10.87)

Age and BMI

Characteristics	HLP	DPP
Age [mean (std)]	44.0 (13.99)	42.4 (14.42)
Baseline BMI [mean (std)]	34.0 (4.8)	36.9 (7.7)
Weight loss	1.2%	2.8%
Increased minutes PA per week	227	145

Dietary Changes

Dietary measure	HLP (n=13)			DPP (n=18)		
	Baseline	12 weeks	22 weeks	Baseline	12 weeks	22 weeks
Fruit, servings/day	1.4	2.6	2.5	1.5	2.2	2.1
Vegetables, servings/day	1.9	2.5	2.5	1.8	1.8	2.0
Sugar sweetened beverages, servings/day	1.8	1.0	0.4	1.7	0.6	0.8
% use of “good” fats most often	42	73	75	46	67	75
% use of “bad” fats most often	58	27	25	54	33	25

Preliminary Findings

- Modest weight loss but significant increase in physical activity and improvements in nutrition in both groups.
- Effect sizes considerably smaller than in more controlled research
- Satisfaction great in both groups
- Small differences between groups make larger trial challenging

Preliminary Findings

- Recruitment hampered by difficulty identifying pre-diabetics and by exclusion criteria
- Randomization and collection of data feasible in this population
- Enrollment low and drop off between enrollment and first session
- Retention and data collection hampered by life circumstances of participants

Challenges

- Implementation challenges:
  - Logistics: job insecurity, childcare, transportation
  - Language and fluency
  - Specificity of target group
- Trial challenges:
  - Identification of pre-diabetics
  - Exclusion criteria
  - Recruitment and retention

Future Directions

- Broaden inclusion criteria for program participation to include metabolic syndrome indicators
- Consider efforts to increase PC identification of pre-diabetics
- Implementation of the DPP in 6 clinical settings – Greater Rochester Health Foundation
- Develop separate trial for HLP / PCORI
- Continue measurement of motivation

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Questions?