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The Effects of Lifestyle Modification on Glycemic Levels and Medication Intake: The Rockford CHIP

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1. Introduction

The high prevalence of cardiovascular disease (CVD) in the past 50 years has led to intense research, resulting in many improvements in treatment. At the same time, type 2 diabetes, with its concomitant increase in vascular complications, has become a serious, exploding, and costly public health concern (1;2).

Diabetes now affects 285 million adults worldwide and 344 million with pre-diabetes. Of these, 25.8 million diabetics and 79 million pre-diabetics are found in the United States alone (3).

The current cost of diabetes in the US is likely to exceed the \$174 billion estimate, which includes 2/3 for direct medical costs and 1/3 for indirect costs, such as disability, work loss, and premature death, but omits the social cost of intangibles (e.g. pain, suffering, lower quality of life) (4-6).

The diabetes epidemic has been accompanied by a similarly drastic increase in obesity. Although the relationship between the two developments is a matter of debate, both are presumably caused by changes in dietary habits and an increasingly sedentary modern lifestyle (7;8). Compelling evidence has shown that lifestyle changes can effectively prevent or delay the occurrence of type 2 diabetes (9-12).

Because individuals at risk for this disease can usually be identified during the pre-diabetic phase of impaired glucose tolerance, early intervention and lifestyle change offer a logical approach to preventing this disease and its devastating vascular complications (13).

Additionally, community-based lifestyle interventions for high risk groups and for the general population are a cost-effective way of curbing the growing burden of the disease (14).

Solidifying the scientific basis for the prevention, treatment and control of this disease and its implementation on a national level, however, remains a difficult challenge (15;16). More research is needed to provide comprehensive and more effective strategies for weight-loss, especially over time (17;18).

Therefore, the objectives of this study were to identify diabetics and those at risk (pre-diabetics) out of the total cohort of 1,517 who selected themselves into an intensive community-based lifestyle intervention program, and to assess its clinical efficacy in effecting medication status as determined and managed by their personal physicians.

2. Methods

CHIP is a 4-week, community-based intensive educational lifestyle intervention program. The project is designed to assess the extent to which a self-selected population can contribute to a shift in coronary risk factors in the community-at-large aiming at primary and secondary prevention.

The participants were recruited from the general population through presentations at service clubs, churches, corporations, as well as through media exposure, billboards, brochures, and healthcare providers.

To be included in the program, participants had to be at least 21 years of age, free of current cancer treatment, at least 3 months post bypass surgery, not afflicted by alcoholism, and able to engage in walking exercises. Eligible and interested participants provided informed consent. All participants were advised to work closely with their personal physicians to monitor clinical changes and to facilitate medication adjustments.

The 40-hour educational intervention with behavioral and skill development content consisted of a carefully crafted 16-session series offered Monday through Thursday for 2 hours over a 4-week period (for details please see Englert et al (19)). Through these almost daily meetings with lectures, clinical Q & A sessions and reading assignments (syllabus, text- and workbooks), the participants became acquainted with some of the extensive epidemiological literature describing the importance of lifestyle factors in the etiology and treatment of chronic circulatory diseases with a focus on a simpler, more *Optimal Diet* used *ad libitum* (20). In addition, several workshops (cooking classes, food-shopping tours, and clinical breakout sessions) were offered during the program to provide the skills needed for adopting a simpler diet. The workshops emphasized the importance of consuming more whole foods, such as fruits and vegetables, legumes and whole-grain products as a way to facilitate lower energy intake with reduced fat ($\leq 20\%$ of total calories), cholesterol (≤ 50 mg), salt (≤ 5 gm), and refined sugar, and enhanced fiber content (>30 to 40 gm) (for details please see Englert et al (21)). Furthermore, the CHIP program promoted smoking cessation and recommended a daily exercise program consisting of 30 minutes of walking and general fitness. At the end of the program, participants were encouraged to join the Rockford CHIP Alumni Organization and attend the monthly educational and support meetings for maintenance.

Prior to the educational intervention, all participants underwent blood testing for fasting glucose and lipid levels, and filled out standardized questionnaires on food and tobacco habits and physical activity. The second biometric assessment took place at the conclusion of the 4-

week program. Patients were screened, questionnaires were completed and blood was drawn by the same trained clinical team to assure standardized procedure for quality control.

As part of the “before” and “after” screening, participants were required to complete a lifestyle/nutrition knowledge test and to fill out personal lifestyle evaluation forms, which included a self-reported medical history, socio-economic details, food-frequency diary, stress level, smoking history, and exercise inventory.

The clinical definitions used for fasting glucose levels are set by the American Diabetes Association (22): normal glucose: <100mg/dl; pre-diabetes: 100 to 125 mg/dl; diabetes: >125 mg/dl.

Weekly physical activity was assessed by frequency and duration of exercise during a usual week: *sedentary lifestyle score 0* (no exercise or at the most 2 times/week for 30 minutes or less than 13 min/day); *moderate score 1* (3 to 5 times/week physical activity for 30 minutes or between 13 and 22 min/day); *optimal score 2* (6 to 7 times/week physical activity for 30 minutes or more than 22 min/day) (23).

2.1 Statistical analyses

The following data are from the *consolidation phase* of the Rockford CHIP research project (19). From the fall of 2000 to the fall of 2002, we conducted 5 CHIP programs, with an average enrollment of 300 per program. Out of a total of 1,569 participants, 52 did not meet the graduation criteria, leaving a cohort of 1,517 men and women for this analysis. In the subgroup analysis presented here, we focused on 758 participants with pre-diabetes and type 2 diabetes (21).

Before each lecture, participants signed in at the registration desk. Those who attended fewer than 13 of the 16 meetings or failed to provide complete clinical data sets did not meet the graduation requirements (drop-outs), and their data were not included in this analysis.

Data were entered twice for accuracy and then analyzed using SPSS 13.0. After testing for homogeneity, the 5 datasets were pooled and analyzed. Paired *t* tests were used to detect before and after changes as continuous variables. McNemar tests were performed for categorical variables and χ^2 -tests for differences in men and women at baseline and after 4 weeks. Analysis of covariance was performed with fasting glucose changes as the dependent variable, and gender, age, and changes in weight (BMI), triglycerides, and physical activity as independent variables.

3. Results

The socio-demographic characteristics of the 758 pre-diabetics and diabetics are presented in Table 1. The gender composition was 432 women and 326 men. The age span ranged from 21 to 81 years. The average age for men was 58 (SD 11) and for women 56 (SD 11). Because no correlation was found between risk improvement and age, data were not age adjusted.

Table 2 depicts the profile of the cohort with reference to diabetes-related risk factors at admission. Of these, 69% were classified as pre-diabetics and 31% as type 2 diabetics, 29% were overweight (BMI between 26 and 30), and 59% were obese (BMI >30). 74% reported a sedentary lifestyle.

	Total (N=758)
Gender	43% men, 57% women
Age (yrs)	58 yrs (men), 56 yrs (women)
Marital status	
married	81%
single	6%
divorced	7%
widowed	6%
Education	
< 12 years	6%
12 years	21%
some college	59%
college or more	14%

Table 1. Socio-demographics: the Rockford CHIP (Illinois, USA)

	Men (N=326)	Women (N=432)	Total (N=758)
Age ≥ 45 years	91%	89%	90%
Pre-diabetes (Glucose ≥ 100 to 125 mg/dl)	66%	71%	69%
Diabetes (Glucose > 125 mg/dl and/or on hypoglycemic medication)	34%	29%	31%
Overweight (BMI between 26 and 30)	32%	26%	29%
Obese (BMI > 30)	57%	61%	59%
Hypertension (SBP ≥ 130 or DBP ≥ 85 mmHg and/or on antihypertensive medication)	87%	79%	83%
Triglycerides (≥ 250 mg/dl)	20%	15%	17%
LDL Cholesterol (LDL ≥ 100 mg/dl and/or on hypolipidemic medication)	90%	86%	88%
Sedentary Lifestyle	67%	79%	74%

Table 2. Diabetes related risk factors of pre-diabetics and diabetics at admission: the Rockford CHIP (Illinois, USA)

Figure 1 shows the flow diagram of the total cohort with reference to pre-diabetes and diabetes after the initial screening. Out of the total cohort of 758 participants, 521 (69%) were classified as pre-diabetics and 237 (31%) as type 2 diabetics. Among the latter group, 154 persons were on medication. A significant number of the 83 diabetic subjects not receiving medication were unaware of their condition. The effects of the CHIP lifestyle intervention program on fasting glucose levels in these participants not taking medication with pre-diabetes ($n=521$) and type 2 diabetes ($n=83$) can be seen in figure 2. Glucose levels improved significantly in both pre-diabetics and diabetics - the higher the initial glucose, the greater the glucose reduction. In many cases, diabetic glucose levels were brought down into the

normal range. Among the pre-diabetics, 47% (25% women and 22% men) were able to lower their glucose below 100mg/dl.

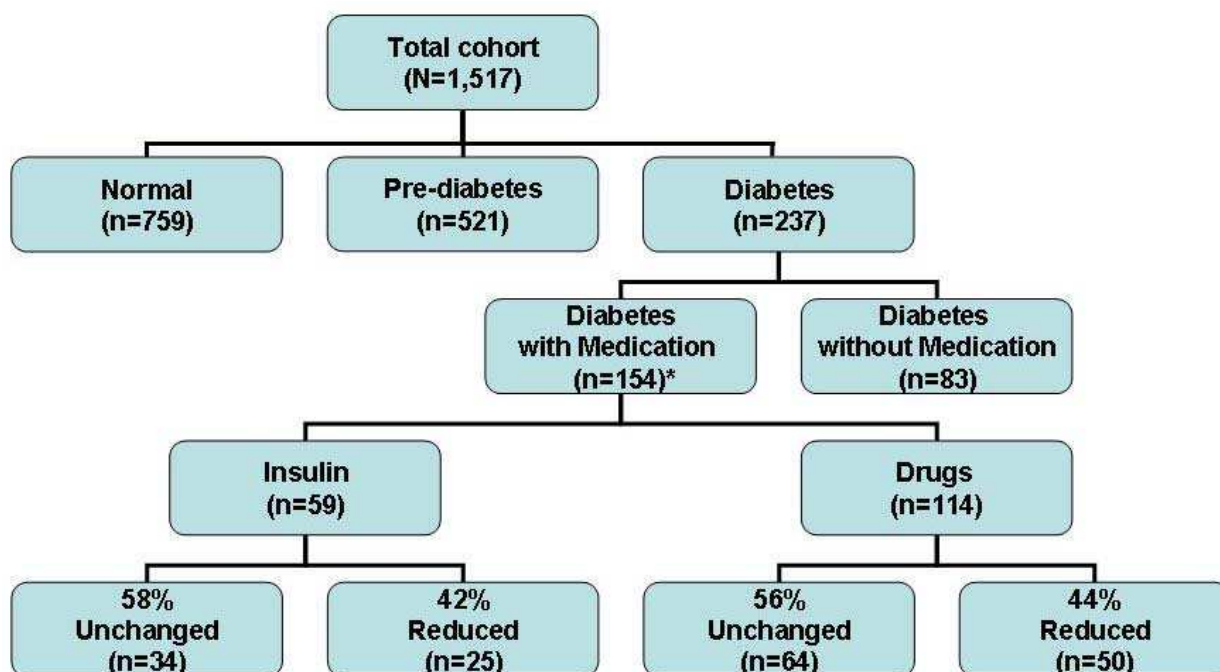


Fig. 1. Flow Diagram according to baseline assessment: the Rockford CHIP (Illinois, USA)

Tables 3 and 4 present the mean changes in fasting glucose in subjects receiving medication (oral hypoglycemics and/or insulin), stratified by gender and medication changes. 44% of those on oral drugs and 42% of those on insulin were advised by their personal physician to reduce their daily medication dosage. In participants whose glucose levels were initially above 125 mg/dl, glucose levels improved on the average between 38 to 49 mg/dl in men and 22 to 27 mg/dl in women. In diabetics with initial levels >125 mg/dl whose medication dosage remained the same, the reductions in glucose levels were equally impressive: the average reduction in men was from 18 mg/dl to 43 mg/dl and in women from 39 to 42 mg/dl. Of those 19 diabetics taking both insulin and drugs, 15 participants were able to reduce their daily doses even so glucose levels dropped by 8 mg/dl and 67 mg/dl in women and men, respectively.

35% of the diabetics were able to reduce their glucose levels below 125 mg/dl. Of these individuals, 10% were even able to reduce them to below 100 mg/dl.

Triglyceride levels in women dropped significantly from 171 mg/dl to 163 mg/dl, and in men from 182mg/dl to 147 mg/dl. LDL levels in women dropped from 122 mg/dl to 112 mg/dl and from 118 mg/dl to 96 mg/dl in men. Moreover average, systolic and diastolic blood pressure was reduced from 140/85 mmHg to 133/79 mmHg in women and 141/85 to 132/80 mmHg in men.

During the 4-week CHIP program, the mean weight reduction was 9 pounds for men and 7 pounds for women. Figure 3 shows that those who needed to lose the most weight lost the most.

	Men (n=57)			Women (n=57)		
	Means			Means		
	before	after	change	before	after	change
Glucose (mg/dl)						
drug dosage reduction*						
≤125 (n=12)	108	123	+15	109	118	+9
>125 (n=38)	166	128	-38	175	153	-22
drug dosage unchanged						
≤125 (n=18)	114	109	-5	114	112	-2
>125 (n=46)	178	135	-43	189	150	-39

* reductions: more than 10% of the daily dose

Table 3. Mean changes over 4 weeks in fasting glucose in diabetics on oral drugs by gender (n=114), according to admission levels: the Rockford CHIP (Illinois, USA)

	Men (n=28)			Women (n=31)		
	Means			Means		
	before	after	change	before	after	change
Glucose (mg/dl)						
Insulin dosage reductions*						
≤ 125 (n=7)	112	107	-5	114	112	-2
> 125 (n=18)	174	125	-49	178	151	-27
Insulin dosage unchanged						
≤ 125 (n=6)	121	105	-16	110	106	-4
> 125 (n=28)	136	118	-18	131	89	-42

* reductions: more than 10% of the daily dose

Table 4. Mean changes over 4 weeks in fasting glucose in diabetics on insulin by gender (n=59), according to admission levels: the Rockford CHIP (Illinois, USA)

Figure 4 shows significant improvements in physical activity. At the beginning of the intervention, 79% of women and 67% of men reported little or no physical activity, 19% and 28% reported engaging in moderate exercise, and 2% and 5% reported engaging in optimal physical activity. After the 4-week program, only 38% of women and 31% of men reported little or no physical activity, 54% and 58% reported moderate physical activity, and 8% and 12% optimal physical activity.

The Analysis of Covariance for glucose changes in participants with pre-diabetes and type 2 diabetes showed significant results for gender ($p \leq 0.001$), BMI ($p \leq 0.001$), and triglycerides ($p \leq 0.001$) but not for physical activity. Improvements in weight and blood glucose were significantly higher in men than in women. In general, after adjusting for gender, reductions in blood glucose were positively related to weight loss - the higher the weight loss, the greater the improvement in blood glucose.

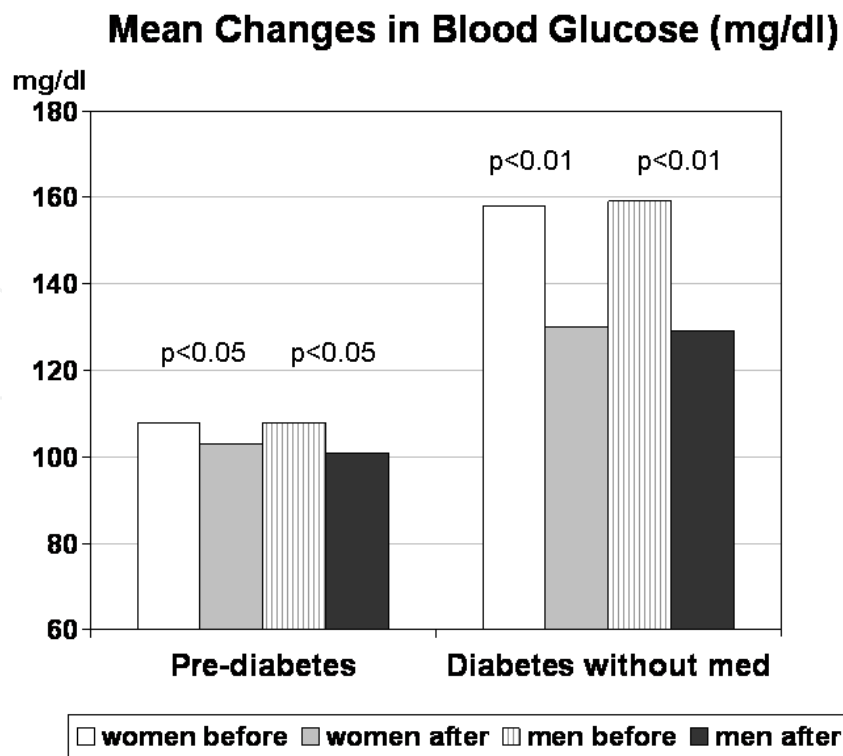


Fig. 2. Mean changes over 4 weeks in fasting glucose in pre-diabetics (n=83) and diabetics (n=521) not on medication: the Rockford CHIP (Illinois, USA)

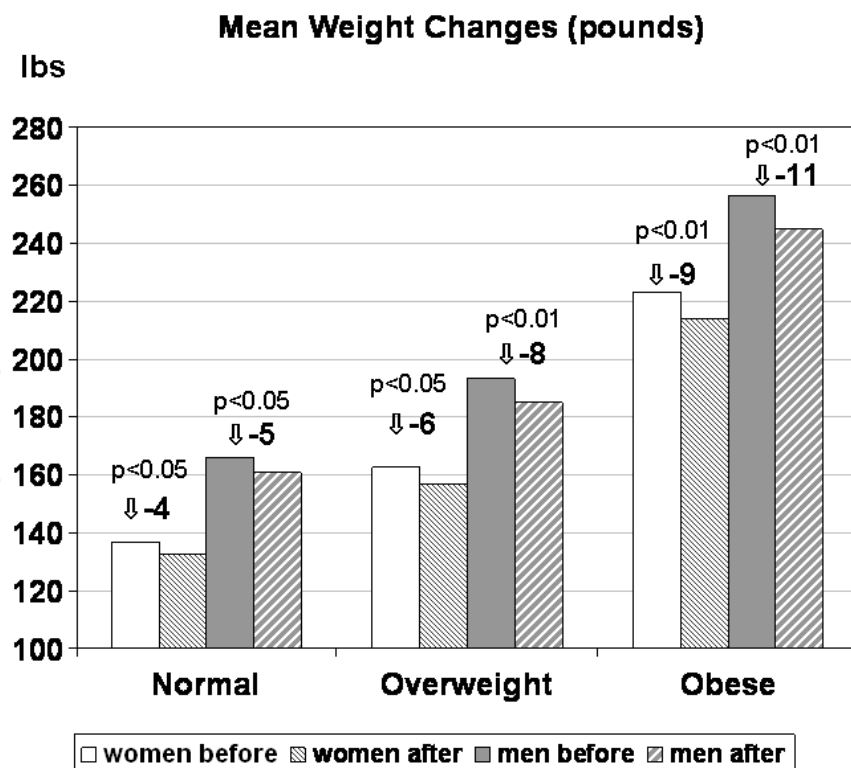


Fig. 3. Mean changes over 4 weeks in weight (pounds) in pre-diabetics (n=521) and diabetics (n=237): the Rockford CHIP (Illinois, USA)

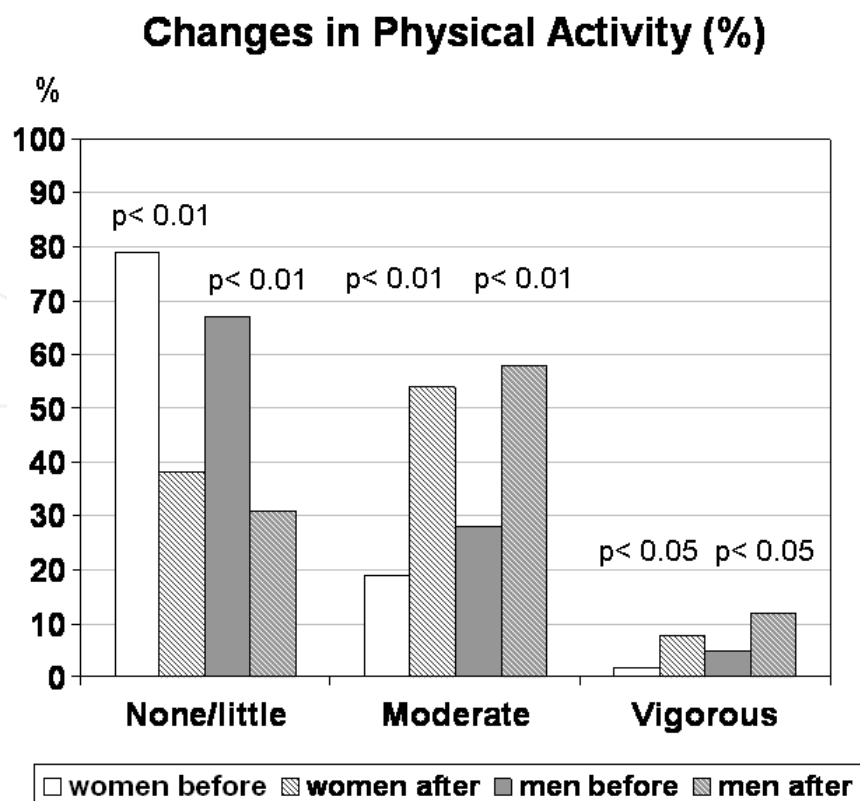


Fig. 4. Changes (in %) over 4 weeks in physical activity in pre-diabetics and diabetics (N=758): the Rockford CHIP (Illinois, USA)

4. Discussion

Primary and secondary prevention of type 2 diabetes is the most promising way to alleviate the ever-growing global burden of this disease (24-26). The aim of this community-based CHIP program was thus to translate theoretical knowledge on the subject into well-defined, real-world strategies for screening and treating a population high at risk for type 2 diabetes.

5. Diabetes risk profile

Half of the total cohort of the CHIP consolidation phase (n=1,517) had already or was at risk for diabetes. This sub analysis showed that 35% of the diabetics had never been diagnosed or received diabetes treatment previously. High rates in diabetes related risk factors such as overweight/obesity (88%), hypertension (83%) and LDL-Cholesterol (88%) is most likely an expression of individual lifestyle choices and the interaction with the environment.

6. Effects of CHIP

CHIP led to an improved risk profile in this high risk patient group. Glucose levels in the pre-diabetics and diabetics who were not on medication improved between 5 mg/dl and 30 mg/dl depending on gender and baseline values.

Similar reductions were observed in the 154 participants who were taking diabetes medication. It is noteworthy that these changes in fasting glucose made it possible – under physicians'

supervision – to reduce the dose of diabetes medication in approximately 40% of cases. Despite this dosage reduction, the decrease in glucose levels was clinically relevant in the majority of diabetics. Eliminating or reducing the intake of these medications is desirable from both a medical and health economic perspective because of their side effects and costs (27).

7. Critical factors of success of the CHIP program

CHIP focuses mainly on 5 process steps: 1) Identification and enrollment of participants with type 2 diabetes or high at risk. 2) Risk profile assessment (HeartScreen-examination). 3) Behavior change (intense, flexible, culturally sensitive, and individualized 16-lesson curriculum that covers diet, exercise, and behavioral modification). 4) Behavior maintenance (alumni groups and supportive community). 5) Evaluation.

7.1 Lifestyle changes

Diet and exercise: There is little discrepancy about the fact that exercise and weight loss play a vital role in the treatment of pre-diabetes and diabetes. Both have been shown to improve insulin resistance and hyperglycemia (16). A review by Miller & Dustan summarizes data on the effectiveness of physical-activity interventions for treating overweight/obesity and type 2 diabetes. Most of the reported exercise-based interventions have been conducted in clinical settings; and they have often required the use of extensive resources (28). In the CHIP-study we recommended a minimum regimen of 30 min/day of moderate-intensity exercise, such as brisk walking (which harmonizes well the recommendations from the American Diabetes Association (ADA) and also the American Association of Clinical Endocrinologists (AACE). There was a significant improvement in physical activity levels in both men and women. In total, 46% of the participants reported that they had increased their level of physical activity to at least 30 minutes a day, or 210 minutes a week. It is noteworthy that, at the beginning of the program, 74% of participants reported no physical activity at all, while at the end only 35% were physically inactive. Tuomilehto et al observed that achieving a relatively conservative target of at least 210 minutes of exercise per week was associated with a significant reduction in the risk of diabetes, even in subjects without weight loss (9).

Depending on initial weight and gender, the CHIP participants were able to reduce their weight within 4 weeks by up to 5%, which approaches the 7% weight loss goal of the ADA for people with diabetes. Exercise, as an integral part of the CHIP intervention, obviously facilitates loss of excessive weight which contributes to improvements in glycemic control and the need for medication (29). While a BMI >30 has been shown to double the incidence of sudden death, and a moderate increase in BMI can lead to a 4- to 8-fold increase in the risk of diabetes, in males and females, respectively, Mobley and coworkers observed the benefits of weight loss on cardiovascular morbidity and mortality (28). Furthermore, weight reduction has been shown to improve endothelial function and decreased systemic inflammatory reaction (30).

While there is little disagreement about the importance of a sensible and consistent activity program in the prevention and management of diabetes, there is still considerable debate about the most effective therapeutic diet. Several authors and study groups have supported the idea that diets low in carbohydrate content yet relatively high in protein and fat may be more beneficial for pre-diabetics and full blown Type 2 diabetics than high carbohydrate diets

since they had been shown to cause hyperglycemia (31-36). Over the years, the ADA gradually reduced their high fat and animal protein recommendations in that they obviously contribute to higher lipid levels thus promoting vascular complications, the very bane of people with diabetes. The ADA also liberalized their once so rigid stand against the intake of sugar and fresh fruits and began to recommend more fresh vegetables and whole grains and more legumes. And yet, while some progress has been made, the current dietary guidelines (recommending the use of meat, poultry, fish and non-rich dairy) are still facilitating an atherogenic diet with up to 7% of the calories consumed coming from saturated fat which also bring along some 200 mg of cholesterol. The current ADA guidelines still reflect the fear of recommending the higher levels of carbohydrate intake, because insufficient attention has been paid to the fundamental difference of how the body handles the digestion and absorption of (1) complex vs. simple carbohydrates (starches vs sugars) and of (2) their unrefined vs refined counterparts (whole grains vs white flour and whole orange vs. orange juice). Unrefined complex carbohydrates with their usually high fiber content become absorbed and digested much more slowly. Thus giving the pancreas more time not to overreact with excessive insulin to reduce the blood glucose levels that usually raise quickly after a slug of sugar, as in a glass of orange juice, where the pancreas has to deal with a highly refined simple carbohydrate totally depleted of any fiber (37).

The CHIP *Optimal Diet* is an “*ad libitum*”, plant-based, very low-fat, low-sugar, high-complex-carbohydrate/low-glycemic, high-fiber regimen with low energy density. In a 22-week clinical trial, Barnard and coworkers were able to show that such a very low-fat plant based, high carbohydrate (70% of calories) diet improved significantly not only the levels of glycemia, but also the levels of lipids and kidney function but clearly exceeded the clinical results of the other intervention diet formulated according to the guidelines of the ADA (38). A recent review concluded that the results from observational and clinical trials demonstrate that low-fat, unrefined plant-based diets are *at least* as effective as more conventional diabetes diets for weight reduction and glycemic control, and that they are significantly more effective in the management of lipid and renal function and in the cost and ease of meal preparation (39).

7.2 Intensive education and curriculum

CHIP is an intensive educational program where participants become aware of the potential benefits of making healthy lifestyle changes and learn how to implement them. The educational curriculum is structured to build progressively and incrementally the concepts of lifestyle medicine. Since habits are best built through daily practice, the program was purposely conducted on an almost every day basis over a period of 4 weeks (40).

7.3 Social support

The group support setting for each of the sessions provided strong social support and may have contributed to the low drop-out rate of 3%.

7.4 Community setting

In the present study we focused on public awareness within the community of Rockford to ensure that individuals high at risk for coronary heart disease and/or diabetes are

sensitized. Our experiences show that a successful health management requires an optimal cooperation of health players in the community. Building up a infrastructure of health-facilitators and multipliers in the community supports the CHIP-philosophy. Effective diabetes lifestyle interventions must target not only the affected individuals, but also families, workplaces, schools etc. Preventing this disease epidemic calls for the identification of culture-sensitive measures that can be applied both to the general population and to high-risk groups. The CHIP strategy is to combine behavior-oriented prevention (e.g. optimal diet, physical activity) with infrastructure-oriented prevention (e.g. supportive community, group support) to promote positive long-term outcomes.

8. Limitations

Self Selection. With its goal of cultural transformation, the CHIP program purposefully aimed at enrolling participants who were probably more motivated and better informed about the need to make healthier lifestyle choices. However, the aim was to build a foundation with motivated people in the community, who, in turn, would become role models in the community-at-large.

Short term results only and lack of control group. It is well known that short-term behavioral changes are subject to decay over time and long-term effectiveness as well as causality cannot be demonstrated without evaluating the program in a randomized controlled trial over an extended period. Moreover, the dimensions to which the CHIP Alumni Association with its refresher courses and monthly meetings can contribute to sustaining these short-term results remain to be subject to further investigation. Even so, the current lack of a randomized control group should not diminish the fact that the vast majority of the subgroup of 758 pre-diabetics and diabetics with multiple risk factors were able to markedly reduce their risk profile in 4 weeks.

9. Conclusion

Diabetes mellitus was very common in this free-living CHIP-cohort with 35% of the individuals being unaware of their condition. The consistently lowered glucose levels in the pre-diabetics and diabetics alike, even in those whose medication dosage had been lowered, suggests that lifestyle changes can be effective in lowering glycemic levels and the need for medication. This lifestyle intervention approach used in a community setting may contribute significantly to reducing the incidence and prevalence of type 2 diabetes at the population level. Until long-term evaluations, however, have been completed, it remains to be seen whether these improvement may **prevent or merely delay** the manifestation on diabetes.

10. Declarations

The study was approved by the IRB of the SwedishAmerican Health System in Rockford, IL, USA.

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None of the authors had a conflict of interest.

11. Acknowledgement

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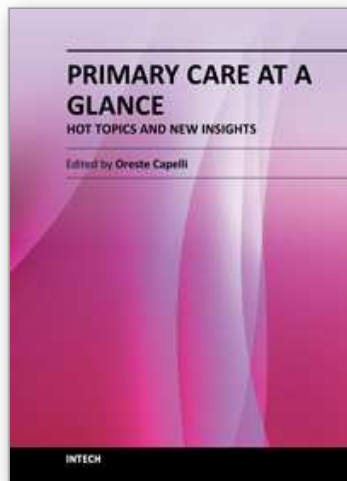
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"Both among scientists and clinical practitioners, some find it easier to rely upon trivial explanations, while others never stop looking for answers". With these surprising words, Augusto Murri, an Italian master in clinical medicine, reminds us that medical practice should be a continuous journey towards knowledge and the quality of care. The book brings together contributions by over 50 authors from many countries, all around the world, from Europe to Africa, from Asia to Australia, from North to South America. Different cultures are presented together, from those with advanced technologies to those of intangible spirituality, but they are all connected by five professional attributes, that in the 1978 the Institute of Medicine (IOM)¹ stated as essentials of practicing good Primary Care: accessibility, comprehensiveness, coordination, continuity and accountability. The content of the book is organized according to these 5 attributes, to give the reader an international overview of hot topics and new insights in Primary Care, all around the world.

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