What are the long term results and determinants of outcomes in primary health care diabetes prevention programme. The DE-PLAN follow up.

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BACKGROUND

- Translational research performed in different settings and populations confirmed findings of RCTs that DM2 prevention through lifestyle interventions can be effective and that results in terms of weight reduction and beneficial cardiovascular outcomes can be sustained in the long term.

- However, results of weight reduction in translational research studies tend to be modest and the proportion of people who can maintain weight reduction is low compared with participants of RCTs.

- There is scientific evidence that maintaining weight loss in the long term decreases the diabetes incidence by up to 89% among individuals at high risk of DM2

- However, long-term weight loss maintenance is achieved only by around 20% of obese people who initially lost weight during lifestyle interventions.

AIM

- **Diabetes prevention in people at high risk is one of the most important challenges in primary health care to decrease the burden and complications of DM2.**

- **Therefore, improvement of the efficacy and effect duration in implementation programs is one of the biggest challenges to public health.**

- **Thus, our objective was to identify factors predicting long-term successful weight reduction maintenance achieved during DM2 prevention programme in patients with high DM2 risk in real life, primary health care setting.**

The DEPLAN

- The DE-PLAN project (Diabetes in Europe: Prevention Using Lifestyle, Physical Activity and Nutritional Intervention) was a translational research study aiming to assess the reach, adoption and implementation of the programme in diverse real life settings in 17 European countries.

- The aim of the DE-PLAN (initiated and sponsored by EU and local governments) was also to create a network of trained and experienced professionals to continue diabetes prevention across Europe

Studied population, methods

- The DE-PLAN project based on the principles of the Diabetes Prevention Study (DPS) examined the intervention implementation in real life settings and hence the design of the study was not randomised.

- The study sample consisted of patients from nine independent Primary Health Care practices in the city of Krakow, Poland. Participants aged over 25 years, with a high diabetes risk corresponding to a score >14 in the Finnish Diabetes Risk Score (FINDRISC) and without previously diagnosed diabetes and without chronic disease which could affect the results of the study were invited to participate in the study.

- Out of 800/566 FINDRISC questionnaires completed, 368 respondents scored >14 and 275 agreed to undergo an oral glucose tolerance (OGTT) examination.

- Subsequently 262 were invited to participate in the lifestyle intervention program.

- 184 participants completed the one-year intervention and 113 of them completed the follow-up examination three years after the baseline examination.

- Nine people (eight with complete measurements) who participated in the three-year follow-up did not participate in the one year examination.

- Information of all three measurements were available of 105 study participants who were included in the analysis.

Intervention

The intervention followed the steps of the Diabetes Prevention Study (DPS) modified and adjusted to the local, primary health care setting.

The main intervention goals:

weight loss

decrease of fat consumption

increase of fruit and vegetable consumption

increase in physical activity

Intervention

The lifestyle interventions were provided by **primary health-care nurses**, two from each health-care practice trained as prevention managers.

One individual and ten **group sessions**, focused on lifestyle changes were provided followed by six telephone sessions and two motivational letters over **a period of 10 months**.

Starting from week four of the intervention patients were offered free of charge **participation in physical activity sessions** twice a week.

There were no other post-intervention contacts with the participants except follow-up measures at years 1 and 3

Measurements, predictors and outcome variables

- Patients were examined at baseline, after 12 and 36 months of the study.

- The examination procedure included: questionnaires (FINDRISC, baseline, clinical and lifestyle and quality of life) and biochemical tests including: fasting and 2-hour post-load glucose, serum triglycerides, HDL and total cholesterol.

- Impaired fasting glucose (IFG) was defined as fasting plasma glucose concentration of more than 6.0 and less than 7.0 mmol/l. Impaired glucose tolerance (IGT) was defined as glucose plasma concentration of more than 7.80 to less than 11.1 mmol/l after OGTT,

- Data regarding education, marital status, employment status, history of increased blood glucose, family history of diabetes, FINDRISC, smoking status, history of hypertension, history of depression were assessed by a self-reported questionnaire.

- Lifestyle changes were measured both during examination after one year as well as during follow-up examination, three years after the baseline examination. Patients completed self-reported questionnaires regarding the consumption of vegetables and fruit, consumption of total fat and saturated fat, change of saturated fat to unsaturated, alcohol consumption and physical activity over the past year.

- Lifestyle goals' achievement was defined as low if 1-3 goals were achieved and high if 4-5 goals were achieved.

- Participants were categorized into two groups based on the weight change achieved at three year examination (two years after discontinuation of intervention):

- those who continued to lose weight or did not change the weight achieved one year after the initiation of the intervention (weight change ≤0; maintainers)

- and those who increased weight during follow up (weight change >0; non-maintainers).

Statistical analyses

- Examinations were performed baseline, after one/three years.
- Coefficients of contingency were calculated to assess correlations between the lifestyle variables (max. C for tables 2 x 2 = 0.707).
- Stepwise regression analysis was used to determine demographic, clinical, and lifestyle predictors of weight reduction maintenance two years after the discontinuation of the intervention
- The covariates for the backward logistic regression model were chosen after revising scientific evidence on risk factors for type 2 diabetes and factors that may predict weight changes during the intervention.

Results

- The patients who completed all three examinations (baseline age 56.6 (standard deviation (SD)=10.7), body mass index 31.1 kg/m² (SD=4.9), FINDRISC 18.6 (SD=3.1))

- **70% participants** showed weight loss during the intervention (mean weight loss **4.2kg (**SD=5.1).

- **37% participants maintained** weight loss during the 3 year follow up(**total** weight reduction **6.54kg**) (**additional** weight loss during the follow up - **2.07kg**(SD=2.3))

- The non-maintainers, on the other hand, returned to their initial weight at the start of the intervention (+0.21 kg). (weight gain during follow up 4.23 kg(3.69))

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Clinical and metabolic characteristic of people who maintained and did not maintain weight loss during follow-up.

|	Baseline			Change from baseline to year 1			Change from year 1 to year 3		
	Maintainers	Non-maintainers	p value	Maintainers	Non-maintainers	p value	Maintainers	Non-maintainers	p value
	Mean (SD[1])	Mean (SD)		Mean (SD)	Mean (SD)		Mean (SD)	Mean (SD)	
Age	58.0 (12.2)	54.7 (9.6)	0.203						
Weight (kg)	84.9 (14.4)	82.8 (15)	0.568	-4.47 (6.63)	-4.02 (3.97)	0.714	-2.07 (2.25)	4.23 (3.69)	<0.001
BMI[2] (kg/m2)	31.2 (4.2)	31.3 (5.2)	0.916	-1.74 (2.36)	-1.47 (1.37)	0.548	-0.69 (0.93)	1.63 (1.44)	<0.001
WC[3] (cm)	99.1 (9.9)	95.5 (11.6)	0.185	-5.93 (5.25)	-4.72 (5.12)	0.338	0.67 (6.02)	4.39 (4.39)	0.007
SBP[4] (mmHg)	131.6 (13.4)	132 (14.9)	0.907	-1.65 (12.19)	-4.57 (18.27)	0.463	2.67 (17.58)	3.49 (16.28)	0.84
DBP[5] (mmHg)	80.8 (7.1)	81.8 (9.7)	0.628	-1.09 (7.36)	-2.86 (9.48)	0.409	-0.41 (6.73)	1.58 (9.47)	0.343
Fasting glucose (mmol/l)	5.2 (0.6)	5.2 (0.8)	0.438	0.1 (0.52)	0.27 (0.74)	0.311	-0.05 (0.62)	-0.12 (0.91)	0.729
2-hour glucose (mmol/l)	5.5 (1.4)	5.8 (1.9)	0.946	0.37 (1.64)	0.07 (2.37)	0.56	0.11 (1.59)	0.34 (1.68)	0.566
TCH[6] (mmol/l)	5.5 (1.0)	5.5 (0.8)	0.878	-0.17 (-0.95)	-0.18 (1.18)	0.977	0.02 (1.17)	-0.11 (1.12)	0.643
HDL[7] (mmol/l)	1.4 (0.3)	1.4 (0.4)	0.733	-0.04 (0.32)	-0.04 (0.27)	0.982	-0.08 (0.31)	0.02 (0.65)	0.459
TG[8] (mmol/l)	1.9 (1.4)	1.5 (0.7)	0.925	-0.31 (1.23)	0.08 (0.74)	0.091	0.03 (0.67)	-0.09 (0.71)	0.481
FINDRISC[9]	19.2 (2.6)	18.3 (3)	0.225	-3.41 (3.78)	-2.91 (3.41)	0.567	0.15 (2.93)\	0.7 (4.47)	0.572

[1]Standard deviation; [2]Body mass index; [3]Waist circumference; [4]Systolic blood pressure; [5]Diastolic blood pressure; [6]Total cholesterol; [7]High density lipoprotein; [8]Triglycerides; [9]Finnish Diabetes Risk Score

Results

- At baseline 15% of the weight loss maintainers and 24% of the non-maintainers had IFG or IGT (p=0.483).

- There were no baseline sociodemografic differences between maintainers and non-maintainers except: Weight loss maintainers had more often baseline history of increased glucose (85% vs 65%, p=0.055).

- During follow-up five people developed diabetes, one of the maintainers and four among non-maintainers (p=385).

Lifestyle changes and lifestyle goals achieved after intervention among those who maintained weight vs those who did not during follow up (one year assessment and three-year assessment.
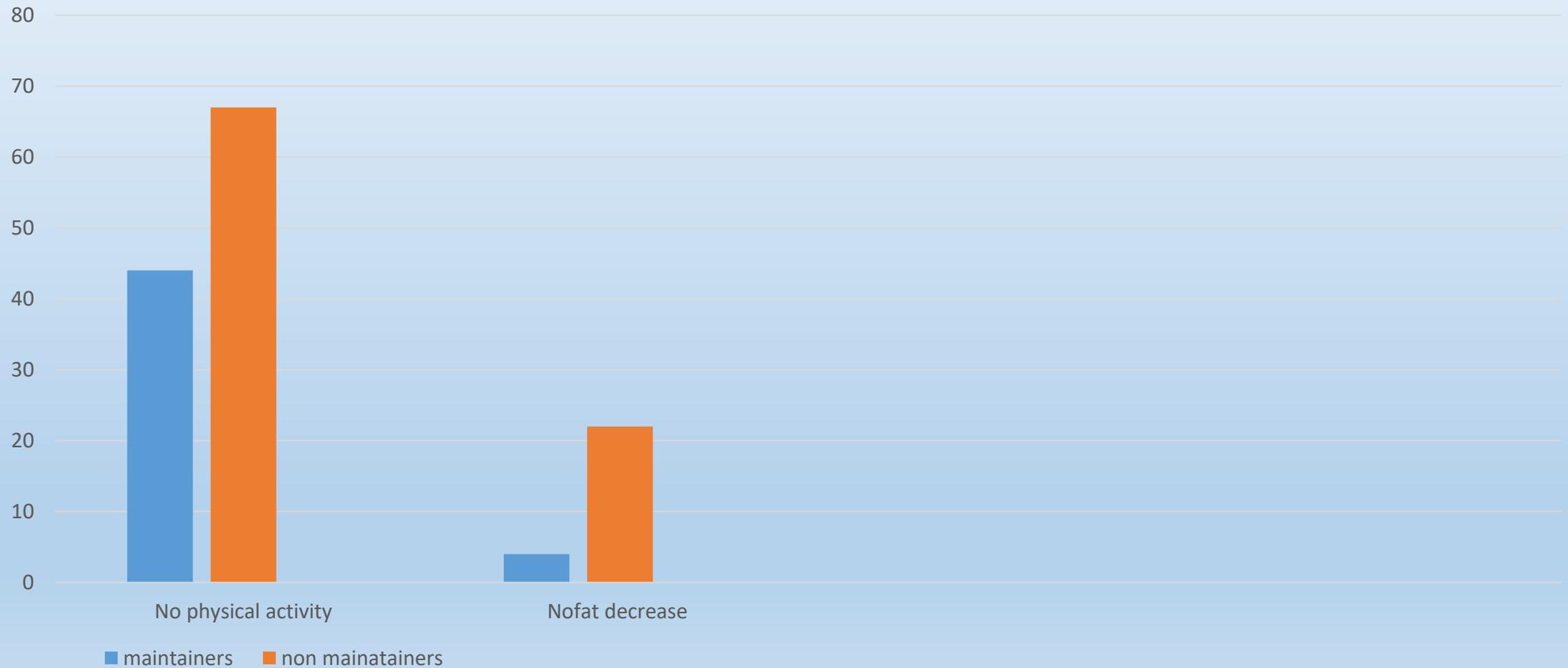
One year assesement
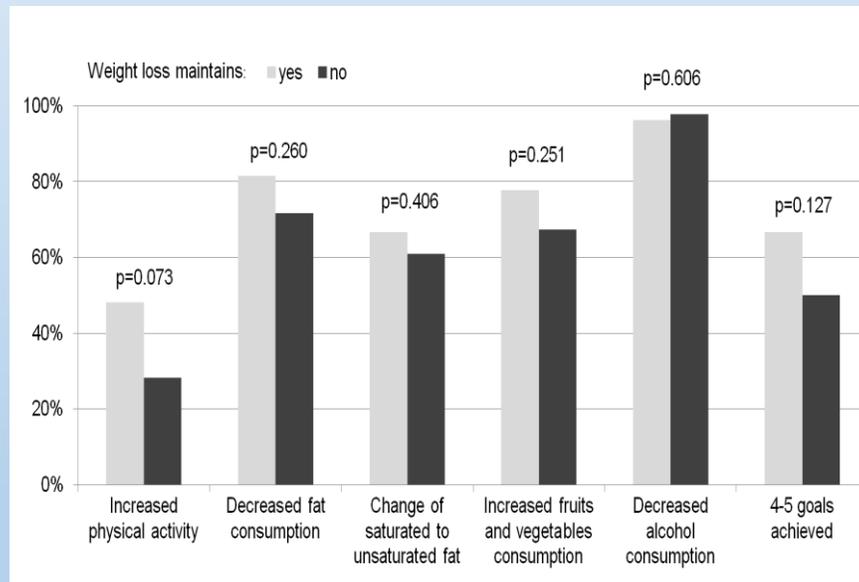
Three year assesement (follow up)
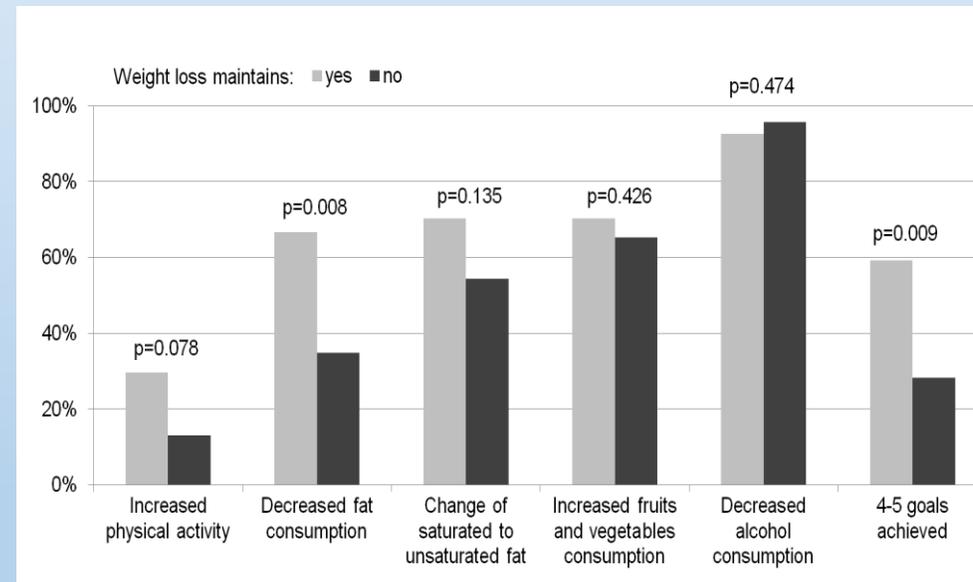
Physical activity and fat consumption not changed both during intervention and follow up period among weigh loss maintainers and non mainatiners

Stepwise regression analysis to determine demographic, clinical, and lifestyle predictors of weight reduction maintenance two years after the discontinuation of the intervention

Unadjusted and adjusted odds ratios of predictors of weight loss maintenance during follow-up.				
	Unadjusted model		Adjusted model	
	OR[1]	95% CI[2]	OR	95% CI
Age	1.04	(0.97; 1.12)	1.03	(0.98; 1.09)
Sex (M/F)	4.61	(0.81; 26.31)	3.87	(0.81; 18.47)
Education (Basic and medium/High)	2.19	(0.32; 15.19)		
Marital status (Married or having a partner/Single or widow)	1.73	(0.41; 7.25)		
BMI[3]	1.05	(0.91; 1.22)		
Waist circumference				
History of Increased Glucose	4.47	(0.75; 26.51)	**4.53**	**(1.13; 18.15)**
Family History of Diabetes	1.49	(0.33; 6.79)		
History of Hypertension	1.19	(0.21; 6.71)		
Smoking currently	1.21	(0.23; 6.50)		
FINDRISC[4]	0.96	(0.73; 1.27)		
Increased physical activity over past year	2.18	(0.49; 9.60)		
Decreased consumption of fat over past year	5.99	(1.17; 30.58)	**4.28**	**(1.41; 12.98)**
Increased consumption of fruit and vegetables over past year	0.46	(0.09; 2.29)		
≥5% weight loss during intervention period	2.18	(0.49; 9.60)		

Summary of results

- **37% participants maintained** weight loss during the 3 year follow up (6.54kg total weight reduction).

- There were no baseline differences between maintainers/non mainainers except more often baseline history of increased glucose (85% vs 65%, p=0.055).

- During the intervention period people who maintained weight loss vs non-maintainers **more often increased their physical activity** (48% vs. 28%, p=0.072). They also continued this lifestyle change during follow up period (30% vs 13%, p=0.078) and more often **continued to decrease fat in diet** (67% vs 35%, p =0.008)

- There were no differences in the number of achieved lifestyle goals after intervention but during follow-up period those who managed to maintain weight reduction **more often achieved 4-5 lifestyle goals** than those who did not (59% vs. 28%, p=0.009)

- 44% of weight loss maintainers and 67% of non-maintainers **did not** increase their physical activity both during intervention and during follow-up (p=0.046), while 4% maintainers and 22% non-maintainers did not decrease total fat in diet in both observation periods (p=0.035)

- In multivariable analysis **baseline history of increased glucose** (odds ratio (OR)=3.7; 95% confidence interval (CI) 1.0-13.6) and **reduction of total fat in diet during follow-up** (OR=4.3; 95% CI 1.5-12.2) were independent predictors of successful weight loss.

Conclusions

- People who manage to maintain long-term weight reduction more often comply to lifestyle goals after the end of the formal study intervention.

- During the intervention period subjects who maintain weight loss vs non-maintainers more often increase their physical activity and continue this lifestyle change during the follow-up period.

- Reduction of total fat in diet during follow-up is an independent and strong predictor of successful long-term weight loss.

- Baseline history of increased glucose is an independent and strong predictor of successful long-term weight loss maintains. Information regarding history of increased glucose, family history of diabetes as well as baseline anthropometric and biochemical results summarized by medical staff should be used to explain the individual diabetes risk as a motivation tool to convince patients to change their behavior.

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- We suggest that medical advice and awareness of the risk of disease are essential to achieve long-term weight loss.

Conclusions

- A deepened insight into participant characteristics, including psychological and behavioural factors, which independently predict weight loss maintenance, is critical for further work of health care providers in real life diabetes prevention initiatives to identify those who are most likely to succeed and to understand barrieres of those who do not succed.

- Novel strategies and designs including extended motivation phase and focus on physical activity modification and individualized intervention should be implemented to improve long-term results of **real life** DM2 interventions.

Thank you