Fundació
La Marató de TV3
22nd SYMPOSIUM
Diabetes and Obesity

DIABETES PREVENTION - TRANSLATING A FEASIBLE AND COST-EFFECTIVE LIFESTYLE INTERVENTION INTO PRIMARY CARE TO REDUCE THE SOCIAL BURDEN OF TYPE 2 DIABETES. THE DP-TRANSFERS PROJECT

Bernardo Costa Pinel

IDIAP Institut d'Investigació en Atenció Primària Jordi Gol – Reus

1. Background

The DE-PLAN-CAT project (Diabetes in Europe–Prevention using Lifestyle, physical Activity and Nutritional intervention–CATalonia) has shown that an intensive lifestyle intervention is feasible in the primary care setting and substantially reduces the incidence of diabetes among high-risk Mediterranean participants. The DP-TRANSFERS project (Diabetes Prevention–Transferring findings from European research to Society) is a large-scale national programme aimed at implementing this intervention in primary care centres whenever feasible (2016-2020).

A multidisciplinary committee first evaluated the programme in health professionals and then participants without diabetes aged 45-75 years identified as being at risk of developing diabetes: FINDRISC (Finnish Diabetes Risk Score)>11 and/or pre-diabetes diagnosis. Implementation was supported by a 4-channel transfer approach (institutional relationships, facilitator workshops, collaborative groupware, programme website) and built upon a 3-step (screening, intervention, follow-up) real-life strategy. The 2-year lifestyle intervention included a 9-hour basic module (6 sessions) and a subsequent 15-hour continuity module (10 sessions) delivered by trained primary healthcare professionals.

A 3-level (centre, professionals and participants) descriptive analysis was conducted using cluster (centre) sampling to assess results and barriers identified one year after implementation. After the second year (screening phase close out), an intermediate analysis was performed to assess the feasibility of the intervention programme. Professional involvement during real clinical practice was estimated by means of quarterly monitoring of programme website activity (data recording and transfer of teaching material). Considering an annual replacement of those centres with low impact, an interim analysis was developed on the basis of the intervention extent and identification of the barriers that opposed the implementation.

The main analysis of the implementation process started after the end of the intervention (2020). The evaluation covers the duration and scope as well as relevant parameters that define the effect of the lifestyle intervention. In parallel, the development of a virtual intervention programme called DP-Transfers-Online

(https://www.dp-transfers.cat) began. The objective is to transfer the lifestyle intervention (basic module) in a non-face-to-face design.

2. Results

Centres and professionals

At 2 years (screening close out), of the 647 registered professionals, 343 (53%) maintained their activity regularly in the programme. Overall, 123 health centres had participated: 40 metropolitan, 44 semi-urban, 39 rural (reference population: 1.6 million). 28 centres (22.8%) either did not start or only participated in the screening, and the intervention was feasible in 95 (77.2%) centres. The transfer to practice was classified as possible (one intervention group) in 39 centres (31.7%), as probable (2 groups) in 37 centres (30%) or effective (3 or more groups) in 19 centres (15, 5%), without finding statistical differences according to geographical area. In summary, preventive face-to-face intervention was feasible in approximately 77% of associated primary care centres, but only 59% of them effectively (or probably effectively) transferred the intensive intervention to routine clinical practice through continued contribution of just 53% of all registered professionals.

Five main barriers to the development of implementation were discussed and prioritized: (1) lack of commitment of healthcare and resource managers, (2) discontinuity of the initial effort and lack of continuity of commitment by professionals, (3) unsustainable increase in professional workload, (4) shift and change in professional status, and (5) lack of acceptance of participants or failure to fulfil the inclusion criteria. However, the responses of 124 active professionals to a programmed voluntary survey showed a high degree of satisfaction with the implementation carried out (4.1$\pm$0.8 points out of a maximum of 5).

Participants and intervention effect

Overall, 2,381 individuals were screened, 1,713 of whom (72%) were accepted to receive the lifestyle intervention and 668 (28%) were excluded either for non-compliance with the inclusion criteria, or for personal or technical reasons (approximately a third for each group). As for the subjects screened, 56% were female; the mean age was 62.6 years, and the mean BMI was 31.3 kg/m2. The BMI

was higher in women but waist circumference (104.8 cm) was higher in men. The presence of cardiovascular risk factors such as hypertension, dyslipidaemia, smoking and a history of ischemic heart disease was significantly higher in men. Diabetes risk was assessed in all cases using the FINDRISC score, and the fasting plasma glucose (PG) test while measuring 2h-PG was only feasible in 2% of all participants. In spite of expected differences in the degree of hyperglycaemia no statistical differences were found in the affiliation parameters (age and sex), clinical or anthropometric between individuals who were excluded or accepted to receive the lifestyle intervention.

Altogether, 1,713 individuals (72%) agreed to receive the intervention (190 groups; 9$\pm$0.8 participants/group). Of these, 532 participants (31.1%) completed only the basic module (2 months), 1186 (69.2%) completed the first year (9.1±4.5 sessions received) and 776 participants (45.3%) concluded the two-year intervention (13.2±2.1 sessions received). Therefore, 937 participants did not complete the entire 2-year intervention, 482 (51.4%) due to technical or infrastructural reasons of the centres or teams, and 455 (48.6%) due to personal causes. The overall median follow-up in intervention (n=1,713) was 15.5 months and the particular median of the group that completed the entire intervention (n=776) was 23.7 months. The sustainability of the intervention over time was significantly lower in the metropolitan settings.

Analyses of changes in risk factors after 2-year follow-up revealed a significant and sustained improvement ($p<0.006$ for all subsequent comparisons) in weight (-2.4 kg), BMI (-0.9 kg/m2), waist circumference (-1.6 cm), diastolic pressure (-1.2 mmHg), fasting plasma glucose (-4.1 mg/dl), total cholesterol (-7.9 mg/dl) and its low-density lipoprotein (LDL) component (-6.2 mg/dl). The 2-year analysis also showed a significant increase in physical activity assessed by the iPAQ scale (8336/1927 points; $p<0.02$); an increase in adherence to the Mediterranean diet measured by the PREDIMED-MEDAS scale (9.1/8 points; $p <0.001$) as well as a relevant increase in health-related quality of life established by the EQ-5D-5L score (73.7/69.8 points; $p<0.001$).

Diabetes (WHO criteria: fasting plasma glucose$\geq$126 mg/dl) was diagnosed in 121 participants (7.06%): 77 (4.49%) during the first year and 44 (2.57%) during the second year. Consequently, the incidence of diabetes during the DP-TRANSFERS intervention was 5.5 cases/100 person-years. The small-scale application of the DE-

PLAN-CAT intervention had already shown a significant reduction in the incidence of diabetes (4.6 cases/100 person-years) compared to the standardized intervention in primary care (7.2 cases/100 person-years). If these data are extrapolated, we now estimate that the large-scale transferred intervention (DP-TRANSFERS) had less impact but also led to a substantial reduction (23.6%) in the incidence of diabetes compared to the standardized intervention.

The Cox proportional hazards model was used to estimate the hazard ratio (HR) for development of diabetes in view of searching for those parameters that could have a consistent and independent predictive value on diabetes incidence. Results from the proportional hazards regression model indicated that hyperglycaemia was the most relevant predictive factor for developing diabetes. The risk of developing diabetes at follow-up increased either with increasing baseline fasting glucose or HbA1c (HR 2.51 [95% CI 1.20, 5.28]; $p<0.02$). The BMI changes (difference between BMI reached at 2 years and baseline BMI) was also an independent predictive factor (HR 1.20 per kg/m2 [95% CI 1.10, 1.31]; $p<0.001$). Regarding a protective effect on diabetes incidence two parameters were found: the high-density lipoprotein (HDL) component of cholesterol at baseline (HR 0.97 [95% CI 0.94, 0,99]; $p<0.03$) and, particularly, the number of intervention sessions received (HR 0.75 [95% CI 0.66, 0.79]; $p<0.001$).

Although the economic analysis has recently started and is still ongoing, the use of personnel resources (time consumed in all programme activities) was 55 minutes per participant in the screening (n=2,381 participants), 872 minutes during the first year (n=1,713) and 412 minutes per participant during the second year (n=776). The corresponding weighted average was 399 minutes per participant (6.6 hours) considering all steps of the programme. Almost 80% of the implementation tasks were carried out by the nursing staff.

Finally, a very important concern was the evaluation of the opinion of participants through a satisfaction survey similar in design to that used for professionals (7 items adapted and scored from 1 to 5). The assessment was clearly positive or very positive in every field considered at any time of the intervention (at 2, 12 and 24 months).

3. Relevance and possible future implications

Relevance of results

Even accepting technical difficulties in transferring the lifestyle intervention (2-year face-to-face design) under real working conditions, a large-scale implementation is feasible among primary care setting. Participants' adherence to the preventive intervention was estimated to be 70% after the first year and decreased to 45% after the second year. The DP-TRANSFERS intervention substantially reduced the incidence of diabetes compared to the standardized intervention. Additionally, the intervention also reduced the impact of those risk factors commonly associated with diabetes.

A large-scale lifestyle intervention in primary care can be properly implemented within a reasonably short time using existing public healthcare resources. Regrettably, the lack of structural, academic and economic incentives as well as the cost associated with the intervention itself had a negative influence on the transfer process. Objectively, a quarter of the centres and almost half of the professionals showed substantial resistance to performing these additional activities. Therefore, a persuasive internet-based facilitation system is being developed and should soon be available.

Capacity building

We have maintained training activities and a representative coordinating committee at all times. In addition to sharing responsibilities by building a permanent structure, a relevant source of data on real-life diabetes prevention has been consolidated. The programme also reinforced a pre-existing international collaboration.

Advancing knowledge

Publications on quality management of diabetes prevention programmes are scarce. The intended set of indicators provide tools to achieving better understanding of the system and to alert about possible areas of improvement. Much work has been carried out using result indicators on a short scale, but there is extremely limited information on the translation process and related costs at national level. The new knowledge achieved will become part of European guidelines on diabetes prevention.

Informing decision-making

The current programme is designed to address presently unanswered public health and policy-relevant questions on diabetes prevention. Our proposal clearly addresses an EU key objective: to promote health, prevent diseases and foster supportive environments for healthy lifestyles ('health in all policies' principle). Primary and specialized health care, researchers, universities and other national stakeholders have been involved from the beginning of the planning. Relationships have been active throughout the process. We also provide an understanding of the preferences of participants for lifestyle-related strategies which is also be relevant in designing future strategies for other chronic diseases in a wider scope.

Health and social Impacts

Screening programmes tend to be warranted, but only if they aim for identification of individuals with high risk of developing diabetes in the future and are complemented with intervention programmes. Otherwise, the potential for prevention remains incomplete and insufficient. Expected outcomes for participants have been increased knowledge about healthy lifestyle, positive changes on self-care adherence, and improvements in overall clinical risk factors. Significantly, the project should provide a better understanding of the interplay of these factors in metropolitan, regional and rural settings across populations of differing socio-economic status and by doing so increase the generalization of the findings.

Economic benefits

Despite the current epidemic context and the improvement in certain countries, the incidence of diabetes does not stop and there will be an increasing need for health services and preventive interventions. Simultaneously, the economic situation in many European countries has forced the governments to cut the health care budgets. Successful completion of this project will allows us to learn and propose an efficient and sustainable health programme that could be replicated and amplified in other countries. In fact, DP-TRANSFERS is a pragmatic example of how to spend smarter but not higher. The project could have an important public health and cost-reducing impact, as population ageing is one of the most important drivers for the increasing number of people with diabetes, and this could be counteracted by postponing the disease to later in life. Additionally, the new developing WEB-based tool should be extendible to promote persuasive lifestyle intervention among new participants.

4. Scientific literature produced

1. Costa B, Castell C, Cos X, Solé C, Mestre S, Canela M et al. Rationale and design of the DP-TRANSFERS project: diabetes prevention-transferring findings from European research to society in Catalonia. J Transl Med 2016;27;14:103. doi: 10.1186/s12967-016-0867-z. Impact Factor: 4.197.

2. Cabré JJ, Martínez A, Mur T, Bonfill M, Barrio F, Costa B y el Grupo de Investigación en Prevención de la Diabetes. El proyecto DP-TRANSFERS de prevención de la diabetes de tipo 2 en Catalunya. Implementación territorial en el sistema público de salud. Endocrinol Nutr. 2017, 64: 44-45. Impact Factor: 1.314.

3. Barrio F, Pujol F, Alum A, Cos X, Martínez A, Costa B y Grupo de Investigación sobre Prevención de la Diabetes. Un nuevo cuestionario de cribado de la diabetes (CATDRISC), derivado del más reconocido (FINDRISC), aumenta su rendimiento en la atención primaria de Catalunya. Endocrinol Nutr. 2017, 64: 46. Impact Factor: 1.314.

4. Grupo de Expertos (Costa B, el proyecto DP-TRANSFERS). Documento de conclusiones del ciclo de jornadas: La gestión del paciente diabético en el marco de la implementación de las estrategias de atención a la cronicidad en España. Promoción de estilos de vida saludables y prevención primaria. Sociedad Española de Medicina de Familia y Comunitaria, 2017.

5. Cos X, Cabré J, Barrio F, Solé C, Castell C, Costa B and the Diabetes Prevention Research Group. The DP-TRANSFERS project for diabetes prevention in Catalonia. Territorial implementation in the public health system. Diabetes 2017 Jun; 66 (Supplement 1): A356. Impact Factor: 8.684.

6. Karamanakos G, Costa B, Gilis-Januszewska A, Velickiene D, Barrio F, Cos X et al. The effectiveness of a community lifestyle intervention programme in the improvement of perceived health status and health-related quality of life. The DE-PLAN study. Diabetologia (2017) 60(Suppl 1): 1. https://doi.org/10.1007/s00125-017-4350-z. Impact Factor: 6.080.

7. Costa-Pinel B,Mestre-Miravet S, Barrio-Torrell F, Cabré-Vila J-J, Cos-Claramunt X, Aguilar-Sanz S, et al. (2018) Implementation of the DP-TRANSFERS project in Catalonia: A translational method to improve diabetes screening and prevention in primary care. PLoS ONE 13(3): e0194005. https://doi.org/10.1371/journal.pone.0194005. Impact Factor: 3,057.

8. Cabré JJ, Barrio F, Cos X, Mestre S, Aguilar S, Costa B, Grupo de investigación en prevención de la diabetes. Implementación del proyecto DP-TRANSFERS en Cataluña: un método de traslación para mejorar el cribado y la prevención de la diabetes en atención primaria. Endocrinol Nutr. 2018, 65: 18. Impact Factor:1.106.

9. Barrio F, Pujol F, Alum A, Roura M, Cabré JJ, Costa B, Grupo de Investigación sobre Prevención de la Diabetes.La nueva escala de riesgo de diabetes CATDRISC (Catalan Diabetes Risk Score) aumenta el rendimiento de la más difundida (FINDRISC) para predecir a 10 años la incidencia de la diabetes. Endocrinol Nutr. 2018, 65: 25. Impact Factor: 1.106.

10. Costa B, Mestre S, Barrio F, Cabré JJ, Cos X, Aguilar S, Solé C, Arija V, Lindström J and the Catalan Diabetes Prevention Research Group. Implementation of the DP-TRANSFERS project in Catalonia: a translational method to improve diabetes screening and prevention in primary care. Diabetes 2018 Jul; 67 (Supplement 1): 2316-PUB. https://doi.org/10.2337/db18-2316-PUB. Impact factor: 7,273.

11. Cabré-Vila JJ, Mestre-Miravet S, Cos-Claramunt X, Martinez-Sánchez A, Barrio-Torrell F, Costa-Pinel B, Grupo de Investigación en Prevención de Diabetes. Dos años de intervención intensiva sobre el estilo de vida para prevenir la diabetes (DP-TRANSFERS). Factibilidad de traslación hacia la práctica real en atención primaria. Endocrinol Diabetes Nutr. 2019;66(Espec Cong 1):36. Impact factor: 1,106.

12. Barrio-Torrell FJ, Costa-Pinel B, Cabré-Vila JJ, Cos Claramunt FX, Castell Abat C, Lindström J, Grupo de Investigación en Prevención de la Diabetes. Reducción persistente a 10 años del riesgo de diabetes tras la intervención sobre el estilo de vida DE-PLAN aplicada en Cataluña. Endocrinol Diabetes Nutr. 2019;66 (Espec Cong 1):37. Impact factor: 1,106.

13. Mur-Marti MT, Cabré-Vila JJ, Costa-Pinel B, Barrio-Torrell F, González-Gil L, Arruego-Casanova M, Grupo de Investigación en Prevención de la Diabetes. Factibilidad y efectividad de la medición de la conductancia electroquímica dérmica para el cribado de neuropatía diabética en atención primaria. Resultados del estudio DECODING. Endocrinol Diabetes Nutr. 2019;66 (Espec Cong 1):58. Impact factor: 1,106.

14. Cabré JJ, Mur T, Costa B, Barrio F, López-Moya C, Sagarra R, García-Barco M, Vizcaíno J, Boneventura I, Ortiz N, Flores-Mateo G, Solà-Morales O and the Catalan Diabetes Prevention Research Group. Feasibility and effectiveness of electrochemical dermal conductance measurement for the screening of diabetic neuropathy in primary care. DECODING Study (Dermal Electrochemical Conductance in Diabetic Neuropathy). J. Clin. Med. 2019, 8(5), 598; https://doi.org/10.3390/jcm8050598. Impact factor: 5,583.

15. Costa B, Mestre S. Traslación a atención primaria de programas de intervención en el estilo de vida para prevenir la diabetes tipo 2 (artículo editorial). Med Clin (Barc). 2019;153(8):323–325. Impact factor: 1,277.

16. Costa B, Mestre S. Transferring to primary care the lifestyle-based type 2 diabetes prevention programmes (editorial). Med Clin (Barc). 2019;153(8):323–325. Impact factor: 1,277.

17. Karamanakos G, Costa-Pinel B, Gilis-Januszewska A, Velickiene D, Barrio-Torrell F, Cos-Claramunt X, Mestre-Miravet S, Piwońska-Solska B, Hubalewska-Dydejczyk A, Tuomilehto J, Liatis S, Makrilakis K. The effectiveness of a community-based, type 2 diabetes prevention programme on health-related quality of life. The DE-PLAN study. PLoS One. 2019 Oct 11;14(10):e0221467; https://doi.org/10.1371/journal.pone.0221467. eCollection 2019. PMID: 31603914. Impact factor: 3,057.

18. Barrio F, Costa B, Cos FX, Cabré J, Martínez A, Mestre S, Castell C, Lindström J, The Catalan Diabetes Prevention Research Group. Ten-Year Follow-Up of Diabetes Incidence in the DE-PLAN (Diabetes in Europe—Prevention Using Lifestyle, Physical Activity, and Nutritional Intervention) Project in Catalonia. Diabetes 2019 Jun; 68 (Supplement 1): https://doi.org/10.2337/db19-1489-P. Impact factor: 7,273.

19. Cabré J, Barrio F, Costa B, Cos FX, Mur T, Martínez A, Mestre S, Castell C, Lindström J, The Catalan Diabetes Prevention Research Group. Ten-year follow-up of diabetes incidence in the DE-PLAN project (diabetes prevention using intensive lifestyle intervention) in Catalonia. Diabetologia (2019) 6 (Suppl 1): S160-161. Impact factor: 6,206.

20. Cabré JJ, Costa B, Cos X, Martínez A, Barrio F, Alum A, Grupo de Investigación en Prevención de la Diabetes. Eficacia y coste de tres modalidades de intervención sobre estilo de vida (presencial, virtual y combinada) para la prevención de la diabetes en atención primaria (Proyecto DP-Transfers-Online). Endocrinol Diabetes Nutr. 2020;67 (Espec Cong 1):66. Impact factor: 1,106.