

BMJ Open Effectiveness of physical activity counselling provided for people with type 2 diabetes mellitus in primary healthcare in North Karelia, Finland: a register-based evaluation study

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ABSTRACT

Objectives Physical activity (PA) plays a significant role in the treatment of type two diabetes (T2D). This study evaluated the effectiveness of PA counselling in primary healthcare (PHC) on clinical outcome measures in patients with T2D, comparing them with a registry-based controls.

Setting The study was carried out in North Karelia, Finland, among PHC clients who have been diagnosed with T2D in 2016–2018.

Participants The study population consisted of patients aged 19–87 years diagnosed with T2D (n=1803). Altogether 546 patients were referred to the PA educator of whom 521 participated the counselling. In totally 1382 sex, age, time of diagnosis and intervention time-matched controls were used to see the effect of intervention.

Interventions Patients with T2D followed up in PHC were offered to participate in PA counselling provided by trained PA educators. The number of counselling sessions and their content were tailored according to patients needs and willingness to participate. To assess the effects of PA to management of T2D clinical outcome measures such as weight and Haemoglobin A1c (HbA1c) and lipid levels were assessed using data from electronic patient records. Each patient was followed up from records at least for a year.

Results Weight and body mass index (BMI) decreased in both groups and mean yearly changes did not differ between the groups. HbA1c levels declined in the intervention and increased in the control group with statistically significant difference in the mean yearly change between the groups (p=0.001). The low-density lipoprotein declined in both groups. The decline was bigger in the intervention group, but the difference did not quite reach the statistical significance (p=0.096).

Conclusions This study shows that PA counselling in PHC offers significant benefits in the treatment outcomes of T2D although no significant declines were not observed in the weight or BMI.

INTRODUCTION

Type 2 diabetes mellitus (T2D) has become a major public health threat; physical inactivity and obesity both being independent risk

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The 'real-world' situation was used, and the results obtained reflect the effectiveness of normal operations in primary healthcare (PHC).
- ⇒ All measurement data were extracted from patient records and thus reflects normal processes in PHC.
- ⇒ In the absence of a traditional study design in this study, the study participation did not influence patients' behaviour.
- ⇒ This study carried out in 'real-world' setting provides valuable additional information on the feasibility of implementation research in PHC and how electronic patient information systems can be used as a source of research data.
- ⇒ Using entirely register-based data increases the amount of missing information.

factors.^{1,2} Risk factors can be influenced by, inter alia, lifestyle changes, such as increasing physical activity (PA) and improving eating habits. In T2D treatment, regular PA combined with a healthy diet and medication are cornerstones of treatment.^{3–5} Increasing daily PA significantly benefits treatment. The use of glucose in skeletal muscle tissue becomes more efficient, and the Haemoglobin A1c (HbA1c) value decreases, facilitating weight management.⁶ In addition, PA improves lipid profile, body fat distribution and blood pressure level.⁷

Regular exercise has been shown to reduce HbA1c levels in patients with diabetes, both alone and in conjunction with dietary intervention.⁸ In meta-analysis, Pan *et al*⁹ reported impact of different exercise training modalities on glycaemic control, cardiovascular risk factors, and weight loss in patients with T2D. They stated that combined exercise showed more pronounced improvement in HbA1c than either supervised aerobic exercise or

supervised resistance exercise alone. Up to our knowledge the effect of PA counselling in management of patients with T2D in real-world setting in primary health-care (PHC) has not been studied earlier.

Implementing lifestyle counselling in clinical practice has been shown to be feasible and cost-effective¹⁰ and acceptable among healthcare professional and patients.¹¹ Evidence-based strategies that can be implemented in clinical practice is among other things, brief behaviour change counselling, group-based education, community referrals and health information technologies.¹¹ There is evidence that more support gives more long-term effect, although it is also evident that rather simple interventions can provide a worthwhile effect.¹²

Lifestyle counselling should be carried out much more effectively as a key component of chronic disease care. Individual PA counselling is helpful for people with T2D, especially for those who were previously physically inactive or with diabetes complications.¹³ Through counselling, PA can be significantly promoted in PHC, but the implementation of counselling is deficient.¹⁴ While dietary counselling is quite well established in PHC, despite special PA guidelines, the implementation of PA counselling has to date been poor. In Finland, intensive PA counselling carried out by a separately trained educators have mostly been experimented in collaborations between PHC and other stakeholders for example referring the patients in need to PA services provided by municipalities or non-governmental organisations.

According to current Finnish treatment recommendations, lifestyle counselling should be a key part of the treatment of patients with chronic illness.¹⁵ However, very little research exists on the feasibility and effectiveness of intensive counselling in PHC. Existing research lacks assessments of the effectiveness of new types of operating models or forms of services as real-world activities.¹⁶ The aim of this study is to evaluate the effectiveness of PA counselling in PHC on management of weight, HbA1c and lipids in patients with T2D, compared with a registry-based control group. The study was conducted as a registry-based evaluation of an intervention in 'real-world' setting that is, PA counselling given as a part of normal service provision.

RESEARCH DESIGN AND METHODS

Participants

All patients with T2D were offered the opportunity to participate in a PA counselling organised in PHC in the Siun Sote region of North Karelia from October 2016 to December 2018. The eligible study population consisted of patients aged 19–87 years diagnosed with T2D. Especially patients with very little PA were referred for PA counselling. Referrals were made by nurses, physiotherapists and physicians meeting the patients in ordinary follow-up appointments. Patients could also make an appointment for PA counselling by themselves (figure 1). Altogether 546 patients were referred to the PA educator.

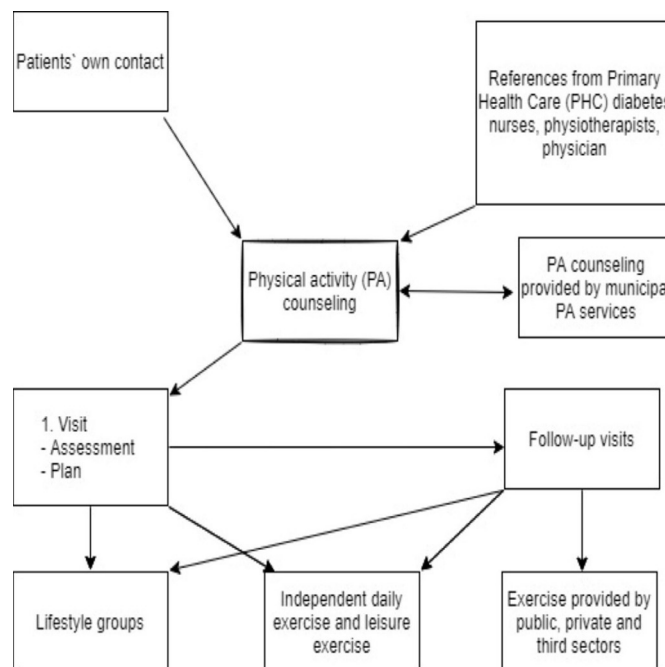


Figure 1 PA counselling service chain in Siun sote region.

Among them, 25 patients did not participate in any counselling contacts and thereafter, the number of intervention participants was 521.

To assess the effectiveness of individual PA counselling, registry-based data were collected from both patients participating the counselling and patients who had not received counselling. The previously established International Classification of Diseases (ICD)-10 diagnoses and/or ICPC-2 (International Standard Classification of Primary Care) codes are entered into the patient information system and patients for this evaluation were identified using these codes (E11 and T90) and information on the type of the visit (appointment at PA educator or other contact). Altogether, 1382 sex, age, time of diagnosis and intervention time-matched patients were identified from electronic health records (EHRs) for controls to analyse the effect of intervention. The survey time was from October 2016 to December 2019. For each patient, the follow-up period for measurements and laboratory results varied based on when they were recruited but was at least one year.

Patient and public involvement

This study is an evaluation study of PA counselling carried out as part of the services provided in PHC to the follow-up of patients with T2D and thus the patients or public could not be involved in planning the intervention protocol. Also, data used in the study are fully collected from registers when the prerequisite for data use is anonymity and no contacts with patients are allowed.

Measurements

For both intervention and control group participants, height (cm) and weight (kg) were measured in health services following the current practice. HbA1c was

analysed using the turbidimetric inhibition immune analysis method. Low-density lipoprotein (LDL), high-density lipoprotein (HDL) and triglycerides (TG) were analysed using photometric direct enzymatic method. All samples were analysed in the same regional laboratory. Information on all physiological and laboratory measurements were retrieved from EHRs retrospectively.

Essential data on patients' situation and contents of individual PA counselling were recorded by educators in the electronic patient information system. The entries were made on a premade template. Information about the participants' PA activity was produced from the descriptive material in EHRs by assessing the written information and coding the activity following predefined rules by researchers. The assessment was made from all visits where information was available. PA level was categorised following the categorisation used in Saltin-Grimby Physical Activity Level Scale¹⁷: 0=no or very low PA, 1=occasionally PA, 2=regularly low-intensity activities (eg, daily walking with dog), 3=regular moderate-intensity leisure time activities and 4=very PA (eg, regular activities on most weekdays). The change in activity level was assessed via the following categories: 0=no change, 1=minor change (eg, increased spontaneous, informal PA), 2=moderate change (eg, started a regular leisure time activity), 3=major change in PA. The effectiveness of PA counselling on physiological and biological treatment outcome indicators was analysed by comparing the follow-up results of those who participated in PA counselling with the data extracted for the control group.

Intervention

Counselling evaluated was given as part of PHC services by educators having training on physiotherapy and motivational interviewing. All individuals in the study population had received PA counselling at least once, either at the reception or by telephone. The first PA counselling visit was made to assess patients' PA level and to plan to increase their activity. On the following visits, the current level of PA was updated and a new plan was made as needed. There was no strictly standardised counselling protocol, but the amount of counselling sessions and contents were tailored taking into account patients' needs. Patients also had an opportunity to participate in various exercise experiments with the PA educator. The PA educator also co-operated with the PA services of municipalities. After the PA counselling visits of the intervention period, the patients were referred to lifestyle groups provided by municipalities or other service providers, or they continued to exercise independently depending on their own motivation and choice (figure 1).

Statistical methods

Basic statistics, such as frequency, percentage, mean, median, SE, minimum and maximum, were used to describe the data. Because of irregularity in measuring frequency, the scope of the linear regression was used to get personal estimates for average yearly changes in

weight, body mass index (BMI), HbA1c, LDL, HDL and TG. The sum of the regression coefficients was also used to calculate estimated values one year after intervention for the same variables. The last measurements before intervention together with measurements after interventions were used in linear regression. Linear and logistic mixed-effects models were used to assess the differences between intervention and control group in mean values and percentages. The R language and environment for statistical computing (V.4.0.3)¹⁸ and IBM SPSS Statistics for Windows (V.27.0)¹⁹ were used in statistical analyses. P values less than 0.05 were regarded as statistically significant.

RESULTS

Population characteristics

The basic characteristics of the participants in the intervention group (n=521) and the control group (n=1382) are shown in table 1. In the intervention group, there were 200 (38%) men and 321 (62%) women. The mean age of the women in the intervention groups was 57 years (range 19–87 years) and of men 56 years (range 19–87 years). In the matched control group, there were 580 (42%) men and 802 (58%) women. Their ages ranged from 19 to 87 years in women and from 19 to 88 years in men. The average number of appointments or other contacts was three contacts per intervention participant. In women, the number of contacts ranged from 1 to 27 and in men from 1 to 12 contacts per person.

Data on PA level was found for 87% (452/521) of those who participated in the intervention. At the beginning of the intervention, 12% of the intervention participants engaged in no PA, 24% of the participants had little PA, 35% of the participants were moderately active, 12% of the participants exercised regularly and 3% of the participants were physically very active. PA data were not available for 13% of the participants. An estimate for the change in PA after the intervention was found for 293 (56%) participants in the intervention group. Among those, 265 (90%) participants had increased PA 34% of participants with information on activity at the end of the intervention had a slight increase in PA, 50% had started a new PA hobby, and 6% of the participants had significantly increased PA during the intervention.

Baseline characteristics (table 1) indicate values for weight, BMI, HbA1c, HDL, LDL and TG at baseline and after the intervention. Data on BMI were available from the electronic patient records for 80% of patients of the intervention group and 55% of patients of the control group, both before and after the intervention. HbA1c and LDL values were available for about 70% of patients in the intervention group and for little more than 60% of patients in the control group. Patients of the intervention group were more obese and had slightly higher HbA1c levels at the beginning of the intervention than the control patients. Thus, the control patients achieved the treatment targets more often than the intervention

Table 1 Baseline characteristics of the study population

	Study group	Measured before the intervention, % (n)	Measured before and after the intervention, % (n)	Values before the intervention, median (min, max)	Values before the intervention, mean (SE)	P value for the difference	Meeting the target before the intervention, % (SE)
Weight (all), kg	I	92 (480)	80 (418)	98 (43, 197)	100.4 (1.0)	<0.001	
	C	66 (906)	55 (766)	90 (39, 238)	93.0 (0.8)		
Weight (men), kg	I	94 (188)	81 (162)	107 (52, 192)	107.8 (1.7)	0.018	
	C	61 (355)	52 (299)	98 (56, 238)	102.6 (1.4)		
Weight (women), kg	I	91 (292)	80 (256)	93 (43, 197)	95.8 (1.2)	<0.001	
	C	69 (551)	58 (467)	84 (39, 179)	86.8 (0.8)		
BMI, kg/m ²	I	92 (477)	80 (416)	35 (17, 65)	35.6 (0.3)	<0.001	5.2 (1.0)
	C	65 (894)	55 (758)	32 (17, 80)	32.3 (0.2)		10.5 (1.0)
HbA1c, mmol/mol	I	81 (420)	71 (369)	46 (27, 130)	50.5 (0.7)	<0.001	65.7 (2.3)
	C	73 (1004)	65 (898)	45 (21, 146)	49.1 (0.4)		73.8 (1.4)
LDL, mmol/l	I	83 (432)	72 (376)	2.6 (0.8, 6.3)	2.84 (0.05)	0.653	40.7 (2.4)
	C	71 (983)	61 (846)	2.7 (0.7, 6.9)	2.86 (0.03)		39.4 (1.6)
HDL, mmol/l	I	55 (284)	30 (154)	1.3 (0.7, 2.7)	1.29 (0.02)	0.398	77.8 (2.5)
	C	48 (658)	30 (410)	1.2 (0.4, 3.1)	1.29 (0.01)		77.2 (1.6)
TG mmol/l	I	51 (277)	28 (146)	1.6 (0.4, 13.0)	1.91 (0.08)	0.849	54.2 (3.0)
	C	45 (646)	29 (404)	1.6 (0.4, 16.0)	2.01 (0.06)		55.1 (2.0)

Target values: BMI <25 kg/m², HbA1c <7.0% or 53 mmol/mol, LDL <2.5 mmol/L, HDL >1.0 mmol/L, TG <1.7 mmol/L.
 BMI, body mass index; HbA1c, haemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; TG, triglycerides.

patients before the intervention. There was no difference in HDL, LDL and TG levels between groups before the intervention began.

Outcome indicators

Table 2 shows changes in weight, BMI, HbA1c and lipid values of those who participated in the intervention and among those in the control group. Weight and BMI declined both in the intervention and control group, but the mean yearly changes did not differ between the

intervention and control groups. HbA1c levels declined in the intervention group and increased slightly in the control group and the mean yearly change was statistically significantly different between the groups. LDL levels declined in both groups, but the difference between groups in the yearly decline was not statistically significant. At the end of the intervention, there were more patients meeting the LDL target compared with the control group, the difference between groups was borderline significant.

Table 2 Changes in weight, BMI, HbA1c and lipid values of persons participating in the intervention and of controls

Variables	Study group	Change per year, median (min, max)	Change per year, mean (SE)	P value for the difference	Estimated* value a year after the intervention, mean (SE)	P value for the difference	Meeting the target a year after the intervention, % (SE)	P value for the difference
Weight, kg	I	0.7 (-41, 38)	1.3 (0.3)	0.297	100.1 (1.1)	<0.001		
	C	0.5 (-118, 25)	0.9 (0.2)		92.3 (0.8)			
BMI, kg/m ²	I	0.20 (-15, 13)	0.48 (0.11)	0.250	34.8 (0.3)	<0.001	4.1 (1.0)	<0.001
	C	0.19 (-38, 7)	0.33 (0.08)		32.1 (0.3)		12.0 (1.2)	
HbA1c, mmol/mol	I	0.19 (-54, 38)	-0.98 (0.43)	0.001	50.4 (0.7)	0.406	63.1 (2.4)	0.003
	C	0.46 (-41, 36)	0.41 (0.21)		49.9 (0.4)		70.6 (1.4)	
LDL, mmol/l	I	0.10 (-11.5, 1.4)	0.18 (0.04)	0.096	2.62 (0.05)	0.112	52.1 (2.4)	0.051
	C	0.05 (-5.2, 4.7)	0.11 (0.02)		2.70 (0.03)		46.6 (1.6)	
HDL, mmol/l	I	0.004 (-0.8, 2.7)	0.008 (0.022)	0.253	1.26 (0.03)	0.976	79.2 (2.4)	0.537
	C	0.010 (-1.8, 0.8)	-0.014 (0.008)		1.26 (0.02)		76.8 (1.6)	
TG, mmol/l	I	-0.01 (0.1, 3.1)	0.08 (0.05)	0.671	1.97 (0.10)	0.720	47.9 (3.0)	0.130
	C	0.02 (0.1, 3.1)	0.17 (0.14)		2.03 (0.08)		55.2 (2.0)	

*The sum of the regression coefficient.
 BMI, body mass index; HbA1c, haemoglobin A1c; HDL, high-density lipoprotein; LDL, low-density lipoprotein; TG, triglycerides.

The proportion of those achieving the target in the intervention group was 41% in the beginning and 52% at the end of the follow-up. The mean yearly changes in HDL and TG levels were minor and non-significant.

DISCUSSION

Up to our understanding this is the first study evaluating the effectiveness of PA counselling in primary care in 'real-world' settings among patients with T2D who were compared with a registry-based control group. The minor weight loss was observed in the intervention group participants, but the difference from the control group was not significant. The primary finding of this study is that HbA1c levels declined in the intervention group and increased in the control group. Also, the proportion of participants who reached the LDL target level at the end of the intervention was higher in the intervention group.

Many studies have reported that T2D is a progressive disease characterised by β -cell failure, and an increase in HbA1c levels is observed over time despite lifestyle and pharmacological measures.^{20–23} So even though the mean decline in HbA1c levels observed in the intervention group in our study was only about 1 mmol/mol/year the result showing stagnation in the deterioration of HbA1c levels can be clinically relevant. The increase in HbA1c levels has been linked to many factors, for example, ageing, the duration of the disease and the severity of the disease.^{24–25} Maintaining good glycaemic balance and avoiding complications requires active monitoring of patients. Support for weight management and other healthy lifestyles, as well as tailoring of glucose-lowering therapies, is necessary.²⁰

Exercise is typically one of the first management strategies recommended for patients newly diagnosed with T2D. Together with diet and behaviour modification, exercise is an important component of all diabetes and obesity prevention and lifestyle intervention programmes. Although there is extensive evidence that exercise is an effective, and affordable approach to prevent and manage T2D, there is still need to win the challenges how to make exercise sustainable for patients.²⁶ Hence, lifestyle behaviour support is a cornerstone in the treatment of T2D in adults.²⁷ In order to make diabetes treatment more effective, patients and healthcare providers should work together to optimise patients' lifestyles from the first comprehensive medical assessment.²⁸ The reason why exercise is not utilised to a satisfactory degree within the clinical care of T2D is multifaceted between a lack of evidence for efficacy in relation to T2D complications and lack of effectiveness trials with satisfactory adherence to exercise. It may be that supervised exercise is needed in the clinical care of T2D and that the degree of support needed to obtain a high level of PA should be remarkable.²⁹ Providing such service in PHC is not easily prioritised.

Umpierre *et al*³⁰ and Boulé *et al*³¹ reported a reduction in HbA1c levels in patients with T2D who participated in

the structured exercise training, which involved aerobic exercise, resistance training or a combination thereof. In these studies, including intensive interventions, the effect in HbA1c was bigger than the one observed in our evaluation. Also, Byrne *et al*³² in their systematic literature review found that self-directed exercise is beneficial for people with T2D to control HbA1c levels preventing the attenuation of HbA1c levels.³² This is very well in line with our findings. Study by Borodulin *et al*³³ supports the importance of PA in glucose control among individuals with obesity. They found that the amount of exercise affects blood glucose levels regardless of obesity.

In this study, in both the intervention and control groups, weight and BMI decreased; however, mean yearly changes did not differ between the intervention and control groups. Ur Rehman *et al*³⁴ found that a supervised structured aerobic exercise programme and routine medication and diet plan had a positive effect on both BMI, dyspnoea and maximal oxygen consumption compared with control group participants treated with routine medication and a diet plan.³⁴ The fact that the intervention studied in the Siun sote primarily supported the self-care of T2D of patients and no intensive supervised exercise was provided in the intervention may explain the fact that there was no bigger change in the weight and BMI of the study participants. Instead, a study by Ur Rehman *et al*³⁴ implemented a supervised structured aerobic exercise programme in combination with routine medication and diet in patients with T2D.³⁴ However, Boulé *et al*³¹ reported in their meta-analyses that the obtained decrease in HbA1c reduces the risk of diabetic complications, although exercise training did not show a significant effect on changes in body weight when exercise groups were compared with control groups.³¹

In turn, Lee *et al*³⁵ studied independent and combined associations of changes in fitness and BMI with all-cause and cardiovascular disease (CVD) mortality in middle-aged men who had undergone at least two medical examinations. They found an association between maintaining and improving physical fitness with a lower risk of CVD mortality in men supporting the evidence that prevention of age-related decline in physical fitness is important for longevity regardless of BMI change.³⁵ Similarly, in our study, even though BMI decline achieved did not differ significantly from control group, the improved PA habits may improve the longer-term outcomes of patients with T2D. This would need to be assessed with longer follow-up of the cohort. Changes in body composition may have occurred, but bioimpedance measurement is not widely used in PHC to detect changes in muscle and fat mass and thus we did not have such information available.

There is strong evidence that a PA lifestyle improves the health and well-being of people with T2D.³⁶ According to current treatment recommendations in Finland, lifestyle counselling should be a key part of treatment in patients with chronic diseases.¹⁵ It is shown that even moderate PA improves treatment outcomes for hypertension, dyslipidaemia and glucose metabolism.^{37–38} In general,



health professionals are positive about PA counselling, but lack of time, low knowledge and doubts about the effectiveness of PA counselling influence attitudes.³⁹ So far, very little is known about the feasibility and effectiveness of intensive PA counselling as part of the multidisciplinary collaboration of chronic disease professionals in healthcare. In Finland, the successful implementation of PA counselling requires a clear process in PHC and co-operation within health centres between healthcare professionals as well as with healthcare and municipal PA services.⁴⁰

Very little implementation research has been carried out in PHC. However, PHC could serve as a rewarding implementation laboratory for various sequential trials of interventions to compare approaches and to examine the mechanisms of action and effect modifiers. Actually, the research resources required for such laboratories are modest given that the health system is already committed to undertaking the interventions and have access to administrative data for the outcome assessment.^{16 41 42} One of the key challenges of performing quality assessment of care or carrying out proper evaluation of experiments in PHC has been poor access to data. A collection of outcome indicators has been conducted separately from the daily work, causing a need for extra resources or inefficient time allocation of professionals.¹⁶ In North Karelia, a joint electronic patient recording system including both PHC and specialised care data was implemented at the beginning of 2010.^{20 43} It enabled rapid access to the data without the involvement of healthcare professionals in data collection.

According to Dunbar *et al*⁴⁴ many translational 'real-world' diabetes prevention programmes have yielded positive results, but they have been small scale. They evaluated the impact of effective and actionable measures on the prevention of diabetes in Australians at risk of developing T2D. In their study, they assessed the effectiveness and feasibility of preventive measures carried out in PHC. According to the study, the resources needed for research and implementation of interventions in a 'real-world' situation are quite modest and thus such approaches can be efficient and affordable.⁴⁴

The strengths of the study are that the 'real-world' situation was utilised, and the results obtained were evaluated so that the effectiveness data is directly comparable with the effectiveness of normal operations. All measurement data were extracted from patient records and thus reflects normal processes in healthcare. In the absence of a traditional study design in this study, the study participation did not influence patients' behaviour. In turn, the absence of the traditional study design and data extraction from the existing patient records resulted in the measurement data remaining partly incomplete. In addition, PA data for controls was not available as it was recorded to patients participating the counselling. One limitation also is that patients participating counselling might be in general more motivated which cannot be controlled in a 'real-world' evaluation study. The motivation level of patients

might have also affected the number of completed counselling sessions.

CONCLUSION

This study shows that PA counselling in PHC, even with modest increases in exercise, offers significant benefits in the treatment of T2D. Although there were no major changes in the weight and BMI of the study participants, the increase in PA is likely to bring health benefits to people with T2D. HbA1c levels decreased in the intervention group and increased slightly in the control group, and the mean annual change was significantly different between the groups. Even a small investment can contribute to the balance of care and quality of life of individuals with T2D. Evidence suggests that complications associated with T2D can be prevented or delayed by improving the quality of diabetes care.

This study carried out in 'real-world' setting provides valuable additional information on the feasibility of implementation research in primary care and how electronic patient information systems can be used as a source of research data. As a further study, it would be interesting to measure longer-term outcomes and the cost-effectiveness of a PA counselling provided in PHC.

Contributors TMM and TL planned the study design. TMM and TL were responsible for acquisition of data. M-LL compiled the data for analyses. M-LL and TMM carried out the statistical analyses. TMM, TL, M-LL, MV and HT participated in the interpretation of the data and TMM drafted the manuscript. All authors contributed to the critical revision of the work and approved the final version of the manuscript. TL is acting as guarantor.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Ethics approval The study was carried out totally as register-based evaluation study. The study protocol was approved by the register administrator, Siun sote. As only pseudonymised register-based data were used and study participants were not contacted the ethics approval nor consent from the patients were not needed according to Finnish legislation.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. The health records data analysed in the current study are confidential and according to the Personal Data Act in Finland cannot be put publicly available to protect the privacy of the patients.

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