The feasibility of a physical activity intervention for adults within routine diabetes care. A process evaluation.

Running head: Process evaluation of PAC within routine diabetes care.

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ABSTRACT

Background: Physical activity is an important factor component in diabetes management but is rarely implemented within routine diabetes care.

Purpose: Explore the feasibility of a 12 month pilot physical activity consultation intervention delivered for adults within routine diabetes care.

Methods: A 12-month pilot physical activity consultation intervention was delivered, including face-to-face consultations at baseline, 6 and 12-months. Additional brief consultations were conducted monthly between baseline and 6-months via either telephone, email or face-to-face. Consultations were led by a physical activity consultant trained and experienced in health psychology and lifestyle behaviour change. Multiple process evaluation measures were conducted including: interviews; email communication; online survey and intervention session summaries. Additional outcomes explored participant characteristics (n=89), attendance, adherence and the feasibility of collecting measurable outcomes for physical activity, BMI, HbA1c and psychological wellbeing. Appropriate methods and outcomes were used to facilitate implementation in a 'real-life' setting, as opposed to typical research settings .

Results: The intervention was feasible with high protocol fidelity, adoption by staff, and positive participant feedback. The role of 'champions' (consultant diabetologist and two health psychologists) was identified as a key factor in the positive evaluation of the intervention. Three changes were made to the intervention to address the complex support needs of the sample. Challenges were identified with collecting questionnaire data within the time allocation of consultations. Although not reaching statistical significance, findings suggest improvements in physical activity levels, BMI and several aspects of psychological wellbeing.

Conclusions: Physical activity consultation is a feasible method of promoting physical activity to adults with diabetes in routine diabetes care. The challenge lies in the translation of physical activity interventions for everyday practice whilst balancing the need for measurable outcomes with effective delivery.

Keywords: physical activity; diabetes; process evaluation; routine diabetes care; translation.

BACKGROUND

Physical activity is an important factor in the management of diabetes. Engaging in appropriate levels of activity can improve insulin sensitivity, facilitate glucose uptake, reduce the progression of diabetes-related complications and all-cause mortality, and have a positive effect on mental wellbeing and quality of life[1]. Despite these benefits most adults with diabetes engage in low levels of physical activity and high levels of sedentary behaviour[2].

Theory based interventions can be effective in achieving greater physical activity and improving health outcomes. A review of seventeen RCT's found that theory based interventions using multiple behaviour change techniques resulted in improvements in both physical activity and health outcomes for adults with diabetes[3]. Incorporating techniques such as goal setting, problem solving, self-monitoring and decisional balance are important facilitators of physical activity behaviour change[4].

Physical activity consultation (PAC) is a theory based intervention, utilising behaviour change techniques shown to be effective for promoting physical activity in people with diabetes[5,6]. These include: goal setting, self-monitoring, decisional balance, enhancing self-efficacy, problem solving, social support, and relapse prevention.Studies have demonstrated success at maintenance of behaviour change up to 24 months[7]. Guidelines for using PAC in people with diabetes have been published[8].

Despite strong evidence for physical activity in the management of diabetes, most published physical activity interventions have been performed in a controlled research setting, with often resource intensive methods, short duration and lack of long-term follow-up[9]. Minimal information is available on how these interventions work within everyday practice[10,11]. A limited number of process evaluations for physical activity interventions within diabetes care have been performed[12,13].

Aim

The aim of this process evaluation was to explore the feasibility of a 12-month pilot PAC intervention delivered within routine care for adults with diabetes.

METHODS

A 12-month intervention was implemented within routine diabetes care. The intervention was designed for: (i) delivery by a qualified physical activity consultant experienced in physical activity behaviour change; (ii) integration with other elements of routine diabetes care; and (iii) to reflect implementation with everyday practice.

Importantly the intervention was implemented not as a research study but as a pilot service for exploration and evaluation. This approach is reflected in the absence of a control group and power calculation.

a) Description of the Physical Activity Consultation Service

Participants and Recruitment

Exclusion criteria was minimal to ensure wide access for all people with diabetes. Adults (≥18yrs, no upper age limit) with type 1 or type 2 diabetes were eligible to participate. This combined approach was chosen to reflect routine diabetes care. People with a contraindication for physical activity were excluded e.g. unstable cardiovascular condition (i.e angina, heart failure, tachycardia) or undergoing laser eye treatment. . The service was publicised by: posters, leaflets and promotion by health professionals in one hospital-based

diabetes clinic and two general practices; newspaper and radio advertisements; and promotion by physical activity instructors at local diabetes exercise classes. Interested patients self-referred by contacting the physical activity consultant directly. Despite introduction of bias, this targeted 'self referral' approach was chosen to reach people with diabetes who were ready to change their physical activity behaviour, improve retention rates, and to minimise the input required by busy health professionals working in a clinical setting.

Physical Activity Consultation (PAC)

The 12-month intervention (Figure 1) was based on PAC guidelines for adults with type 2 diabetes[8]. This intervention was guided by the Transtheoretical Model of Change (TTM)[14], and supported by behaviour change strategies identified in the Behaviour Change Technique Taxonomy[4]. All consultations were delivered by an accredited Health Psychologist with qualifications and experience in exercise and health Psychology.

Training of other health care professionals (i.e dieticians, physiotherapists, nurses) should be explored. The physical activity consultant was originally funded to deliver the intervention for 4-hours per week, which after several months was increased to 11-hours per week for the remainder of the intervention. This time allocation reflected the limited funding secured from NHS Grampian Endowments and a Paths for All grant for pedometers.

Participants received an initial 30-min manualised face-to-face consultation. This included assessing current activity levels, past and present activities; pros and cons of being more active; advice on hypoglycaemia risk and referral to diabetes specialist nurse team (if appropriate) overcoming barriers; recommendations for increasing physical activity (frequency, duration and intensity), writing down goals, planning social support and relapse prevention; The initial consultation was followed by five monthly shorter follow-up

consultations delivered via participants chosen method of contact (face-to-face, telephone or email). Follow-up consultations were participant-led and varied in format and duration (approximately ten minutes per follow up) depending on stage of change and the level of support required. Two further face-to-face 30-min consultations were undertaken at both 6-months and 12-months. Between 6 and 12-months no formal contact with participants was made; however, participants were encouraged to contact the physical activity consultant for advice if needed. Maintenance of behaviour change was encouraged via the use of specific behaviour change strategies (e.g. relapse prevention) in addition to decreasing frequency of contact over time[15].

Resources

Throughout the 12-month intervention participants were encouraged to increase their physical activity to meet the current UK recommendations of 30-mins of moderate physical activity on at least 5 days per week[16]. Keeping participants clinically safe was a priority. Relevant health care professionals involved in supporting the patient (i.e GP, Diabetologist; Dietician) were informed of the intervention. Participants were encouraged to increase their physical activity but only to a level which was comfortable for them. Most participants were encouraged to gradually reach accumulated extra activity on 5 days a week or more. Hypoglycaemia risk (during or after exercise) was explained to patients taking sulphonylureas or insulin. As a group the risk of hypoglycaemia was not high as only 27% were on insulin. Participants were advised to speak with their diabetes nurse to get advice, ifdosage adjustment was required. Participants were advised to choose activities they enjoyed. Participation in local diabetes exercise classes was recommended and walking was encouraged as a cheap and effective form of activity[17]. Pedometers (SilvaEx10) and step diaries were provided and participants

were encouraged to self-monitor their daily step count and set achievable walking goals. For example 1500 steps (approximately fifteen minutes of activity broken down in five minute chunks). A physical activity resource booklet detailing various local activity opportunities was provided.

Measurable Outcomes

Physical activity levels in addition to some physical and psychological outcomes were assessed. Measures were chosen to minimise the challenge of obtaining data in everyday practice. Physical activity was measured at baseline, 6 and 12-months using the International Physical Activity Questionnaire-Short Version (IPAQ-S)[18]. Stage of change was assessed by asking "Would you say you are thinking about increasing your activity or ready to change/increase your activity?" and additional questions which assessed their motivation and confidence for increasing or maintaining their level of physical activity. Body Mass Index (BMI) and HbA1c were obtained at baseline and 12-months from routine data stored on a central computer data system. Routine HbA1c data was not updated on SCI Diabetes as often as anticipated and it was often hard to identify a 6 month mid point in routine data. Therefore focus was given to collection of 12 month data. Psychological wellbeing was measured at baseline, 6 and 12-months using the Positive and Negative Affect Scale (PANAS)[19], and the Hospital Anxiety and Depression Scale (HADS)[20]. Participants were encouraged to monitor their weight and self-report this data at each follow-up. Data were analysed using repeated measures ANOVA (using SPSS Version 21.0) and reported as mean and standard deviation.

b) Description of the Process Evaluation

A process evaluation, guided by the World Health Organisation[21] and Steckler and Linnan[22], was performed by an independent researcher not involved in delivery of the intervention.

Multiple process evaluation measures were collected during the initial 30-months of the intervention. Measures were chosen to minimise participant burden and reflect the setting of everyday practice. Three 1-hour semi-structured interviews were undertaken with the physical activity consultant delivering the intervention to explore issues of implementation and protocol fidelity. Additional qualitative insight was gained from local health professionals (n=10) and participants (n=6) via telephone interview, email correspondence or online survey, regarding their experience of the intervention. Interviews were transcribed verbatim and analysed for process information related to the feasibility, implementation and adoption of the intervention. A session summary, capturing data on each consultation, was recorded by the physical activity consultant. A data input spread sheet was used to record additional information e.g. attendance, missed appointments, reasons for non-attendance. Session summaries and the data input spread sheet were analysed for process data related to fidelity and implementation. Qualitative and quantitative data were then collectively analysed to identify key issues related to delivery of the intervention in practice.

Ethical approval was granted by the North of Scotland Research Ethics Committee. Informed consent was obtained from all individuals in the study.

RESULTS

Participant characteristics

A total of 89 participants enrolled in the intervention during the initial 30-months of recruitment. Enrolment was on an ongoing basis and at the time of data analysis 89 participants had baseline data, 53 participants had reached 6-month follow-up, and 35 participants had reached 12-month follow-up. Funding for continuing the pilot service then ended. It had been anticipated that further funding would be secured, however given the

current financial climate this was not the case and the final participants were unable to complete the follow-up time points. The difference in numbers at baseline, 6 and 12-months therefore reflects the nature of rolling recruitment and not attrition.

At baseline participants had a mean age 59.5 (SD 11.3) years; mean BMI 34.1 (SD 7.8) kg/m2; mean HbA1c of 62.6 (SD15.5) mmol/mol (7.9±3.5%); mean years since diagnosis was 11.4 (SD11.4) years; 82.0% (n=73) had type 2 diabetes; 18.0% (n= 16) had type 1 diabetes; 49% (n=44) were female; 58% (n=52) had multiple comorbidities (including obesity; osteoarthritis; COPD; cancer; heart conditions; chronic fatigue; depression and anxiety) 59% (n=53)were from the two least deprived areas as assessed by the Scottish Index of Multiple Deprivation. All participants were of Caucasian origin. No information was collated on medication, other than insulin use. Future research should include this data.

Most participants self-referred after receiving an information leaflet from diabetes health professionals or the local diabetes exercise class (49.4%, n=44) or were referred by primary or secondary care health professionals (46.1%, n=41). The remaining participants self-referred following a press release or by word of mouth (5.6%, n=5). Of the participants who self referred, three patients were excluded due to 1) an active foot ulcer, 2) not ready to change physical activity level and 3) required further psychological support.

Attendance and participation

Seven participants withdrew before 6 month follow-up, and one participant withdrew before 12 month follow-up. Reasons for attrition were ill health (n=5), work commitments (n=1), child care issues (n=1) and relocation (n=1). The remaining participants attended all three face-to-face PACs. Between baseline and 6-months all participants received monthly contact

with the physical activity consultant. Preferred method of follow-up contact was telephone 45.1% (n= 37 of 82) and email 54.9% (n= 45 of 82).

Protocol fidelity

The physical activity consultant kept a summary of session content to assess protocol fidelity. Fidelity was observed with participants receiving all components of the intervention at each time point. Behaviour change techniques included were: goal-setting cards; problem solving sheets; and the provision of pedometers and step diaries for self-monitoring.

Three protocol adaptations were required to ensure effective delivery of the PAC in practice. Firstly, allocation of 30-minute for each PAC was insufficient and was increased to 45-minutes. Secondly, many participants were of older age, had multiple co-morbidities and required more intensive support (including relapse prevention; planning social support; setting and adjusting physical activity goals). The gap of 6-months between the initial and follow-up consultation was too long. An additional 30-min PAC at 3-months was offered to participants requiring greater support (ten participants (11.2%) accepted the additional face-to-face consultation). Finally, a follow-up telephone call was added one week after the initial PAC, to ensure patient understanding.

Issues regarding implementation

Access to good local activity facilities including diabetes-specific activity sessions and health walks provided by the Paths for All Partnership played a key role in the intervention. Many participants attended the diabetes exercise classes (38.2%; n=34 of 89). Patients attending the diabetes exercise classes tended to be more able and achieved better outcomes. They

highlighted the classes provided a source of social support, peer advice and diabetes education

Pedometers were identified as effective for self-monitoring and forming intentional behaviours. Participants used pedometers to profile their activity, set progressive and achievable goals, and increase their self-efficacy. We did not record if use of pedometers tailed off towards the end of the intervention. Lack of administration support was identified as the main barrier for ongoing intervention delivery. This was partly addressed by the provision of minimal secretarial support from 12-months onwards, which assisted with the preparation of letters to participants' health care providers, and sending email updates to relevant staff.

Insight from participants and health care staff

Insight was gained from six participants who had completed the 12-month intervention. Responses were gathered from participants who had (n=4) and had not achieved (n=2) greater physical activity levels or weight loss. They all reported high satisfaction with the intervention and identified several factors that contributed to their positive experience. Firstly, the approachability and helpfulness of the physical activity consultant delivering the intervention was highlighted. Secondly, the provision of pedometers and step diaries was considered motivational, informative and useful. Finally, participants who did not achieve greater physical activity levels or weight loss highlighted ill-health and impaired mobility as the main barrier. All participants found the intervention beneficial and would recommend the service to others.

Insight was gained from ten health professionals regarding their adoption of the intervention within primary and secondary care. All health professionals agreed that the intervention

complimented current diabetes care. Health professionals adopted and promoted the intervention for several reasons. They considered the intervention protocol to be of a high standard; the service integrated well with current diabetes care; referral to the service was not time-consuming; and positive patient feedback was received. They also valued the expertise of the physical activity consultant and identified the important role of 'champions' for the service. The 'champions' (a Consultant Diabetologist and two Health Psychologists) provided an easy route to promote the service e.g. attendance at regular staff meetings in both primary and secondary care; use of existing electronic communications and shadowing of both primary and secondary care patient consultations.

Feasibility of measurable outcomes

This unpowered study did not attempt to assess the effectiveness of the intervention but rather feasibility of obtaining measurable outcomes. Table 1 presents results for interest. In brief, they demonstrated an: increase in the number of participants achieving the physical activity recommendations; an increase in stage of physical activity behaviour change; a reduction in self-reported weight; an increase in positive affect (PANAS); a reduction in levels of depression (HADS); and a decrease in BMI. Although we did not collect a detailed recording of adverse events, none of the participants specifically reported an adverse hypoglycaemic event related to increasing physical activity.

Several issues with obtaining measurable outcomes were identified. These included: (i) lack of time within consultations to complete questionnaires; (ii) a lack of time to look at data on medication use; (iii) routine BMI and HbA1C data not being updated on the central computer system as frequently as anticipated, leading to missing follow-up data; and (iv) challenges with completing the detailed IPAQ data within the time-constraint of the consultations. Rather than calculating the estimated minutes per day spent in various intensities of physical

activity, the physical activity consultant briefly discussed with participants whether they were achieving the current UK physical activity recommendations[16]. The outcome was therefore amended to reflect participants who were and were not achieving the physical activity recommendations at baseline, 6-months and 12-months.

DISCUSSION

This study demonstrated that a PAC intervention within routine diabetes care can be a feasible method of promoting physical activity. The intervention was delivered with high protocol fidelity and positive feedback from both participants and health professionals. Several aspects of the intervention may have contributed to its feasibility in practice. Firstly, the intervention was delivered by an experienced physical activity consultant/ accredited health psychologist . Whilst an expensive resource, participants reported their relationship with the Health Psychologist as a key factor in their positive experience of the intervention. The role of Health Psychologists in supporting physical activity behaviour change for diabetes has not been previously explored. Health Psychologists are trained to work with patients to improve self management across a range of long term conditions. (e.g. monitoring/testing, decision-making, administering treatments or engaging appropriately with health care systems. also to work with patients on emotional wellbeing and stress reduction strategies). They can work alongside other diabetes care health professionals to provide an integrated approach to diabetes management. Their knowledge and skills in complex behaviour change may be beneficial for individuals with diabetes who require intense support due to multiple comorbidities[23].

Secondly, the individual approach of the PAC provided one-to-one support for many participants with complex support needs. This is supported by findings from the *Time2Act* study[24] where, despite no overall difference in physical activity being observed for participants receiving a face-to-face PAC, a significant increase was found for a sub-group of participants with low physical activity levels at baseline. This suggests that one-to-one

support delivered in person was most beneficial for individuals requiring additional support to change their behaviour.

Participants also had the opportunity to gain further support from a group environment by attending the diabetes exercise classes or health walks. Group settings are known to provide peer motivation and support and have been effective in achieving greater physical activity levels in adults with diabetes[25].

Thirdly, flexibility in the method of monthly follow-up allowed participants to have autonomy over their preference for support. Participants could tailor their monthly follow-up to suit their individual circumstances. The ability to contact participants via email or telephone allowed the service to continue at a comfortable rate without creating a back-log of participants waiting for face-to-face appointments.

Finally, the intervention was integrated with other aspects of routine diabetes care. It reinforced messages by other health professionals (e.g. dietary education) and did not operate as a 'stand-alone' service. Health professionals highlight that whilst they are aware of the need for physical activity promotion but often struggle to provide tailored information within relatively short diabetes consultations as well as long-term support and do not have the confidence to effectively promote physical activity,

Consequently, the intervention was well received and adopted by health professionals within both primary and secondary care, reflected in the rate of referrals received from health professionals. Recruitment of 89 participants, despite limited time resources of 4-11hrs per week, is encouraging. If delivered on a full-time basis this intervention had the potential to support 364 participants per year.

The intervention was based on a theoretical framework of behaviour change[14] and evidence-based guidelines for the delivery of PAC for people with diabetes[8]. A range of behaviour change techniques were used, supported by the Behaviour Change Technique Taxonomy by

Michie et al[4] and research by Avery et al[3]. Pedometers were particularly effective for self-monitoring and forming intentional behaviours. Previous research has shown pedometers to be effective in achieving greater levels of physical activity in people with type 2 diabetes in both the short term and long-term[25]. Their feasibility in this sample of mainly older adults with multiple comorbidities is encouraging. Formally collecting pedometer diaries may be a more feasible method of assessing change in physical activity rather than completing the IPAQ in this sample. Participants in this study required support to complete many of the questionnaires. This was not feasible within the PAC timeframe and is an aspect of the study that requires further consideration for future work.

Although the study was not powered for effectiveness it demonstrated promising findings in relation to clinically meaningful outcomes. Individuals with type 2 diabetes, who are often sedentary and overweight, are known to achieve metabolic improvements from small changes in physical activity[26].

Several minor adaptations were made to the intervention protocol to ensure effective delivery of the intervention. Each of the adaptations increased the intensity of support received by participants, factors identified in previous research as important in both achieving and maintaining behaviour change[15]. A review of physical activity and dietary interventions in the general population found that maintenance of behaviour change was associated with interventions that included face-to-face contact, were greater than 6-months duration, included brief follow-up throughout the intervention, and used greater than six behaviour change strategies[15]. This intervention achieved each of these criteria.

Strengths and limitations

This is the first process evaluation performed in the UK exploring the implementation of a physical activity consultation intervention within routine diabetes care. Reporting bias was

minimised by the evaluation being undertaken by an independent researcher. Due to the nature of rolling recruitment and limited funding the process evaluation was conducted at a time when not all participants had reached 12-month follow-up.

CONCLUSIONS

Physical activity consultation, delivered by a skilled health professional, can be a feasible method of supporting people with diabetes and multiple co-morbidities to change their physical activity behaviour. These promising findings now need exploring further in a powered trial assessing the effectiveness of physical activity consultation interventions delivered within routine diabetes care. The focus of this process evaluation was to explore feasibility of delivering a physical activity consultation intervention within routine diabetes care, to see if health professionals and patients would refer and participate and to explore how the intervention could be delivered. Future research should explore how to adapt this intervention for cost effective delivery within routine care. The challenge lies in the translation of physical activity interventions for everyday practice whilst balancing the need for measurable outcomes with effective delivery.

Health professionals or researchers involved in the development of future physical activity interventions should consider integrating their intervention protocol with other aspects of diabetes care, such as, dietary advice and self-care education. Training other health professionals to deliver the PAC intervention would keep costs down. An emerging theme at present is the development of social prescribing (i.e. linking patients with non medical sources of support in the community). Exploring how the PAC intervention could fit into the social prescribing model would also be worthwhile.

Competing interests: The authors have no competing interests.

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REFERENCES

1. Colberg SR, Sigal RJ, Fernhall B, Regensteiner JG, Blissmer BJ, Rubin RR, et al. Exercise and type 2 diabetes: the American College of Sports Medicine and the American Diabetes Association: joint position statement executive summary. Diabetes Care. 2010;33(12):2692-6. Epub 2010/12/01
2. Plotnikoff R, Karunamuni N, Courneya K, Sigal R, Johnson J, Johnson S. The Alberta Diabetes and Physical Activity Trial (ADAPT):A Randomized Trial Evaluating Theory-Based Interventions to Increase Physical Activity in Adults with Type 2 Diabetes. Ann Behav Med. 2012;Epub 25th August
3. Avery L, Flynn D, van Wersch A, Sniehotta F, Trenell M. Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. Diab Care. 2012;35(12):2681-9
4. Michie S, Ashford S, Sniehotta F, Dombrowski S, Bishop A, French D. A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALORE taxonomy. Psychol Health. 2011;26(11):1479-98
5. Kirk A, MacMillan F, Webster N. Application of the Transtheoretical model to physical activity in older adults with Type 2 diabetes and/or cardiovascular disease. Psychology of Sport and Exercise. 2010;11(4):320-4
6. Jackson R, Asimakopoulou K, Scammell A. Assessment of the transtheoretical model as used by dietitians in promoting physical activity in people with type 2 diabetes. Journal of Human Nutrition and Dietetics. 2007;20(1):27-36
7. Di Loreto C, Fanelli C, Lucidi P, Murdolo G, De Cicco A, Parlanti N, et al. Validation of a counseling strategy to promote the adoption and the maintenance of physical

activity by type 2 diabetic subjects. Diabetes Care. 2003;26(2):404-8Kirk AF, Barnett J, Mutrie N. Physical activity consultation for people with Type 2 diabetes: evidence and guidelines. Diabet Med. 2007 Aug;24(8):809-16Kavookjian J, Elswick B, Whetsel T. Interventions for being active amoung individuals with diabetes: A systematic review of the literature. Diab Educ. 2007;33:962-88

8. Dzewaltowski D, Glasgow R, Klesges L, Estabrooks P, Brock E. RE-AIM: Evidence-Based Standards and a Web Resource to Improve Translation of Research Into Practice. Ann Behav Med. 2004;28(2):75-80
9. Matthews L, Kirk A, MacMillan F, Mutrie N. Can physical activity interventions for adults with type diabetes be translated into practice settings? A systematic review using the RE-AIM framework. Translat Behav Med. 2013; Published online 29th September 2013, do 10.1007/s13142-013-0235-y
10. Two-Feathers J, Kieffer EC, Palmisano G, Anderson M, Janz N, Spencer MS, et al. The development, implementation, and process evaluation of the REACH Detroit Partnership's Diabetes Lifestyle Intervention. Diabetes Educ. 2007;33(3):509-20. Epub 2007/06/16
11. Unsworth M, Slee R. Evaluation of the Living with Diabetes Program for People with Type 2 diabetes: East Metropolitan Population Health Unit 2001-2002. Perth, Western Australia: 2002
12. Prochaska J, Velicer W. The Transtheoretical Model of Health Behavior Change. American Journal of Health Promotion. Health Promot. 1997;12(1):38-48
13. Fjeldsoe B, Neuhaus M, Winkler E, Eakin E. Systematic review of maintenance of behavior change following physical activity and dietary interventions. Health Psychol. 2011;30(1):99-109. Epub 2011/02/09

14. Department of Health. UK Physical Activity Guidelines: Technical Report. London: 2011

15. Shaw R, Fenwick E, Baker G, McAdam C, Fitzsimons C, Mutrie N. 'Pedometers cost buttons': the feasibility of implementing a pedometer based walking programme within the community. BMC Pub Health. 2011;11:200

16. Craig C, Marshall A, Sjostrom M, Bauman A, Booth M, Ainsworth B, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc. 2003;35(8):1381-95

17. Watson D, Clark L, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. J Pers Soc Psychol. 1988;54(6):1063-70

18. Bjelland I, Dahl A, Haug T, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. J Psychosom Res. 2002;52(2):69-77

19. World Health Organisation. Process Evaluations: Workbook 4. Geneva: World Health Organisation; 2000

20. Steckler A, Linnan L. Process Evaluation for Public Health Interventions and Research. San Francisco: Jossey-Bass; 2002

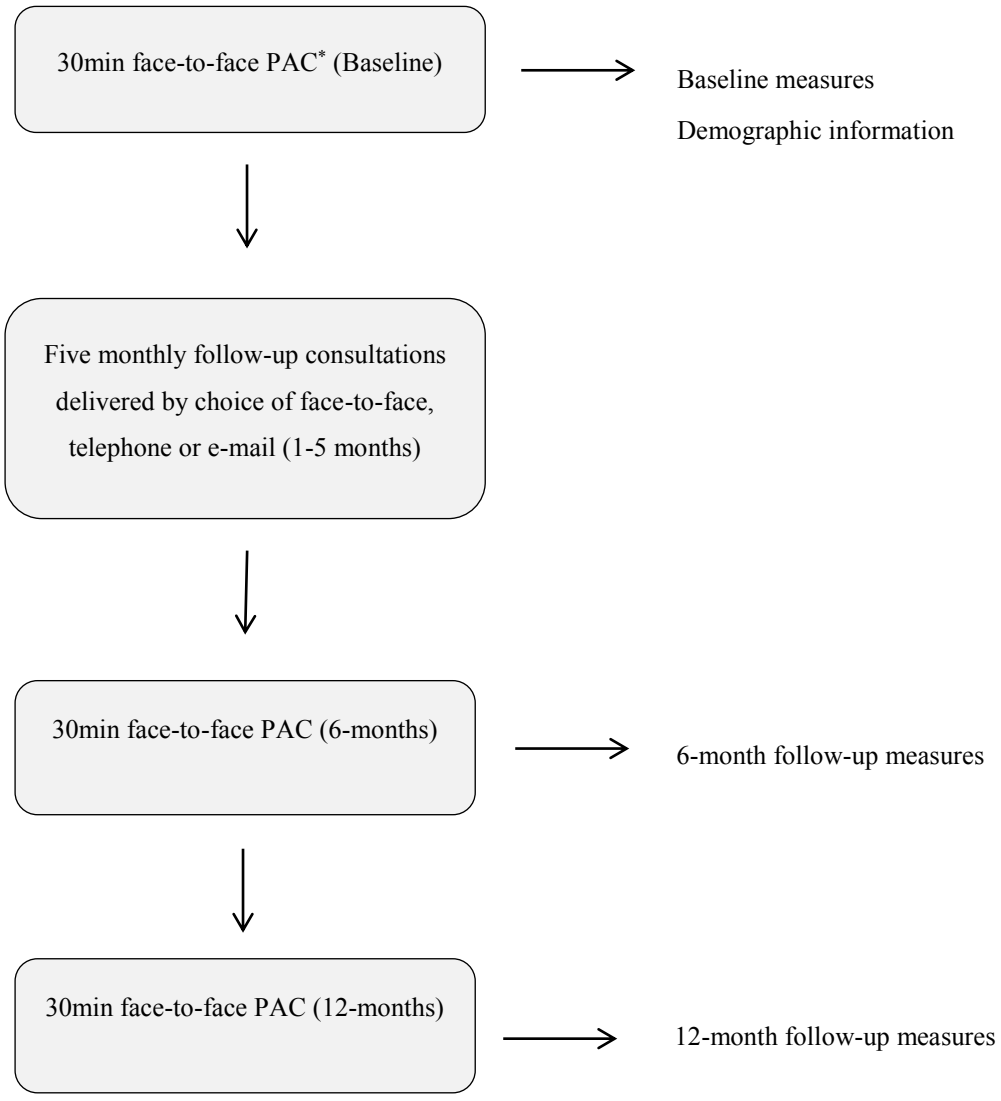
21. Keogh K, Smith S, White P, McGilloway S, Kelly A, Gibney J, et al. Psychological family intervention for poorly controlled type 2 diabetes. Am J Manag Care. 2011;17(2):105-13.Cobiac L, Vos T, Barendregt J. Cost-effectiveness of interventions to promote physical activity: A modelling study. PLoS Med. 2009;6(7):e1000110

22. Kirk A, Barnett J, Leese G, Mutrie N. Twelve Month Changes in Physical Activity and Quality of Life Outcomes Following a Physical Activity Consultation Delivered in Person or in Written Form in Type 2 Diabetes. The TIME2ACT Study. Diabetes. 2009;58:A97-A

23. Tudor-Locke C, Bell R, Myers A, Harris S, Ecclestone N, Lauzon N, et al. Controlled outcome evaluation of the First Step Program: a daily physical activity intervention for individuals with type II diabetes. Int J Obes. 2004;28:113-9

24. Colberg, SR. Physical activity: the forgotten tool for Type 2 diabetes management. Front Endocrinol. 2012;3:70

Figure 1. Intervention timeline. (to be attached as a separate file)



*PAC: Physical Activity Consultation

Table 1. Mean (SD) data for physical activity, PANAS, HADS, BMI, HbA1c and weight at baseline, 6 and 12-months.

Outcome	*Baseline*	*6-months*	*12-months*	*Normative values*
% of participants meeting the PA° recommendation [18]	14.6% (n=89)	68.8% (n=48)	78.0% (n=35)	N/A
Self-reported weight (kg)	96.5 ± 19.7	86.4 ± 29.4 (n=47)	92.3 ±19.6 (n=27)	N/A
BMI from clinical records (kg/m2)	34.1 ± 7.8	N/A	32.2 ± 7.2 (n=35)	≥30: obese
Depression (HADS)	5.1 ± 3.7	3.9 ± 4.4 (n=38)	2.7 ± 2.1 (n=31)	≥8 indicates depression
Anxiety (HADS)	5.6 ± 3.8	6.0 ± 5.5 (n=40)	4.7 ±3.2 (n=23)	≥8 indicates anxiety
Positive Affect (PANAS)	30.5 ± 6.9	32.1 ± 8.5 (n=40)	34.6 ± 7.2 (n=26)	Higher values indicate greater positive affect
Negative affect (PANAS)	17.2 ± 6.7	16.5 ± 7.5 (n=41)	14.8 ± 6.6 (n=27)	Lower values indicate greater negative affect
HbA1c (mmol/mol)	62.6 ± 15.0 (7.9±3.5%)	N/A	61.4 ± 16.4 (7.8±3.7%) (n=34)	≥48.0 (6.5%): diabetes

°Physical activity