Behavioural interventions to promote physical activity in a multiethnic population at high risk of diabetes: PROPELS three-arm RCT

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Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

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Scientific summary

PROPELS three-arm RCT

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Scientific summary

Background

Type 2 diabetes is a leading cause of mortality and disability globally, accounting for significant health resource expenditure. The risk of diabetes can be reduced through increased physical activity. However, systematic reviews have identified limitations in the evidence as to whether or not previous diabetes prevention programmes have been successful at promoting physical activity behaviour change in the long term. There has been a particular lack of research assessing the effectiveness of physical activity interventions in minority ethnic groups, such as South Asian people, who are known to have a substantially elevated risk of developing type 2 diabetes.

Walking Away from Type 2 Diabetes (Walking Away) is a low-resource, group-based behavioural intervention designed to promote physical activity in those at risk of developing diabetes within primary care. Walking Away has already been commissioned into routine care pathways for the prevention of diabetes. This research sought to develop an integrated mobile health (mHealth) intervention to support the maintenance of behaviour change within Walking Away, and then test whether or not Walking Away promotes sustained increases in physical activity in a multiethnic population with and without the addition of the developed mHealth intervention.

Objectives

The preliminary objective was to develop a tailored mHealth intervention to provide follow-on support for participants referred to the Walking Away programme. The primary objective was then to investigate whether or not Walking Away can lead to sustained increases in physical activity after 4 years in an ethnically diverse population at high risk of type 2 diabetes, when delivered at two levels of ongoing follow-on maintenance support (with and without the developed mHealth intervention). This primary objective was supported by key secondary objectives, which were to compare the effectiveness of the tested interventions in white European and South Asian subgroups and to conduct a within-trial and long-term economic evaluation of each tested intervention.

Methods

Design

This was a three-arm, parallel-group, pragmatic, superiority randomised controlled trial. Treatment allocation was carried out using a web-based randomisation procedure provided by the Leicester Clinical Trials Unit, with equal allocation probabilities. Follow-up was conducted at 12 and 48 months. The primary outcome was objectively assessed ambulatory activity (steps per day) at 48 months. A total of at least 1308 participants was required to meet the sample size specifications.

Setting

Research was conducted at the Diabetes Research Centre, University of Leicester, and the MRC Epidemiology Unit, University of Cambridge. Participants were recruited from primary care or previous research cohorts and intervention delivery was conducted in community or health-care settings adjacent to participants' general practices.

Participants

Participants were recruited from across Leicestershire and Cambridgeshire. The primary method of recruitment was directly through primary care using patient records: eligible participants were identified by their general practice and were sent an invitation letter and study information sheet by post. In Cambridge, participants who met the inclusion criteria were also recruited from existing population-level research studies. Participants were recruited if they had a blood glucose or glycated haemoglobin (HbA_{1c}) value that indicated an elevated risk of type 2 diabetes (referred to as prediabetes) within the last 5 years. This was defined as fasting glucose of $\geq$ 5.5 mmol/l and $<$ 7.0 mmol/l, 2-hour post-challenge glucose of $\geq$ 7.8 mmol/l and $<$ 11.1 mmol/l, or HbA_{1C} of $\geq$ 6.0% (42 mmol/mol) and $<$ 6.5% (48 mmol/mol). Other inclusion criteria were being aged 40–74 years (25–74 years if South Asian) and having access to a mobile phone and being willing to use it as part of the study. Those who were unable to take part in walking activity, were pregnant or were unable to provide informed consent were excluded.

Interventions

Control

Participants were provided with an information leaflet targeting knowledge and perceptions of diabetes risk and the importance of physical activity in reducing risk.

Walking Away

A low-resource, 3-hour, group-based behavioural intervention aimed at targeting knowledge and perceptions of risk factors for type 2 diabetes, outcome expectations around the effectiveness of physical activity at managing those risk factors, physical activity self-efficacy, and the promotion of specific behaviour change techniques centred on the provision of pedometers to support goal-setting and self-monitoring. Walking Away was delivered by two trained educators to groups of up to 10 participants. Participants were also invited to attend 2.5-hour group-based refresher sessions at 12, 24 and 36 months.

Walking Away Plus

Participants were invited to attend the Walking Away programme and the annual refresher sessions as described above. They were also provided with additional follow-on support in the form of a tailored mHealth intervention that was developed specifically to be integrated with Walking Away. The mHealth intervention involved participants regularly texting their individual goals and their achieved daily steps to an automated system, which responded with tailored text messages targeting attitudes and beliefs, motivation, self-efficacy and continued use of behaviour change strategies. Participants were also given support in the form of telephone calls from trained educators at 1 week and 6 months following each annual group-based session.

Outcomes

The primary outcome was overall ambulatory activity (steps per day) at 48 months, measured using a waist-worn accelerometer (ActiGraph, ActiGraph, LLC, Pensacola, FL, USA), which also provided the time spent sedentary, along with time in light-intensity physical activity and moderate- to vigorous-intensity physical activity as secondary outcomes. In addition, a thigh-worn accelerometer (activPAL) provided the time spent sitting or lying, standing and walking. Physical activity was also measured by self-report (Recent Physical Activity Questionnaire). Intervention process measures relating to self-efficacy, illness perceptions and use of behaviour change strategies were captured by self-report. HbA_{1C} and other standard clinical biochemical and anthropometric variables were also assessed.

Embedded qualitative substudies were also undertaken to provide qualitative insights. These used focus groups and telephone interviews and focused on the two novel aspects of the PROPELS intervention: its duration, and the provision of maintenance support through telephone calls and text messaging. Their aim was to further the understanding of influences on engagement with the

intervention; whether or not and how participants reported the intervention helping them to increase and/or maintain physical activity; and how participants and educators thought that the intervention might be improved.

The cost-effectiveness of the trial interventions was assessed by conducting two separate health economic analyses. The primary analysis was a model-based analysis using the School for Public Health Research Diabetes Prevention Model, which extrapolated trial outcomes over a lifetime horizon. The secondary analysis was an evaluation of the within-trial costs and outcomes, which assessed the costs and benefits of the interventions for the 4-year follow-up period of the trial, including costs per quality-adjusted life-year using utility scores derived from the EuroQol-5 Dimensions (EQ-5D). Both analyses took an NHS and Personal Social Services perspective. Costs for both analyses were valued in 2017/18 Great British pounds. Unit costs were obtained from nationally representative sources such as the NHS reference costs.

Results

We randomised 1366 individuals (median age 61 years, median body mass index 28.4 kg/m^2, median ambulatory activity 6638 steps per day, women 49%, black and minority ethnicity 28%), of whom 460 were allocated to control, 450 were allocated to Walking Away and 456 were allocated to Walking Away Plus. Approximately 80% attended the initial group-based behavioural intervention in both arms, with 78% of participants in the Walking Away Plus arm also registering for the text messaging service. Waist-worn accelerometer data were available for 1017 (74%) and 993 (73%) individuals at 12 and 48 months, respectively.

At 48 months, neither arm showed differences in objectively measured ambulatory activity compared with control [Walking Away Plus: 121 steps per day, 97.5% confidence interval (CI) −290 to 532 steps per day; Walking Away: 91 steps per day, 97.5% CI −282 to 463 steps per day]. This was consistent across ethnic groups.

Measures of self-reported physical activity (metabolic equivalent minutes per week, time in moderate to vigorous physical activity and time walking) were not significant at any time point, except for an increase in self-reported physical activity of 4.4 (97.5% CI 0.0 to 8.8) kJ/kg/day in the Walking Away Plus arm at 48 months.

At the intermediate, 12-month, follow-up, there were no differences in the Walking Away arm compared with the control arm in any of the objectively assessed or self-reported physical activity variables. However, participants in the Walking Away Plus arm were found to have increased their ambulatory activity by 547 (97.5% CI 211 to 882) steps per day compared with those in the control arm, and had increased their time spent walking by 8.5 (97.5% CI 3.3 to 13.7) minutes per day and in moderate to vigorous physical activity by 3.5 (97.5% CI 0.6 to 6.5) minutes per day compared with those in the control arm. In addition, at 12 months, participants in the Walking Away Plus arm had been 1.61 (97.5% CI 1.05 to 2.45) times more likely to achieve 150 minutes per week of unbouted moderate to vigorous physical activity than participants in the control arm.

In the Walking Away Plus arm, triglycerides were reduced at both 12 months (mean intervention effect −0.15 mmol/l, 97.5% CI −0.29 to −0.01 mmol/l) and 48 months (mean intervention effect −0.11 mmol/l, 97.5% CI −0.21 to 0.00 mmol/l) compared with control. The Walking Away arm lost around 1 kg in body weight at 12 and 48 months compared with control, with reductions observed in waist circumference and improvements seen in markers of liver function. Other lifestyle, anthropometric and biochemical variables were unchanged in both the Walking Away and the Walking Away Plus arms at 12 and 48 months compared with the control arm, as were symptoms of anxiety and depression.

Despite the lack of an intervention effect at 48 months, rates of self-reported engagement with the key behaviour change techniques were notably higher in the intervention arms than in the control arm. At 48 months, 64.2% of participants in the Walking Away Plus arm and 49.7% of participants in the Walking Away arm reported using a pedometer at least some of the time, compared with 19.7% in the control arm. Similarly, 40.9% and 30.6% in the Walking Away Plus and Walking Away arms, respectively, reported keeping an exercise log at least some of the time, compared with 11.1% in the control arm, and 78.8% and 73.0% in the Walking Away Plus and Walking Away arms, respectively, reported setting themselves exercise goals, compared with 64.0%% in the control arm. However, participants in all arms reported high levels of self-efficacy in engaging on physical activity at baseline, and these levels remained high throughout the intervention.

The findings from the embedded qualitative study also suggested that participants actively engaged with the interventions and found the experience positive, with the tailored mHealth follow-on support reported as being helpful. However, a common theme was that that major illnesses, injury or life events that had occurred during the 4-year trial period in this older population had caused relapse and discontinuation with the programme, after which it was hard to re-engage.

The real-world costs of delivering Walking Away and Walking Away Plus were estimated as £257 and £322 per person, respectively. The probabilistic lifetime costs of Walking Away and Walking Away Plus (£22,945 and £23,018, respectively) remained higher than those of standard care (£22,598). Lifetime cost-effectiveness modelling over a 30-year horizon suggested that standard care had the highest probability of being cost-effective below a threshold of £20,000 per QALY. It was further estimated that, to reach a threshold of £20,000 per QALY, the Walking Away Plus arm would have to be delivered at a maximum cost of £116 per person. However, there was a high level of uncertainly in these estimates, with the value-of-information analyses indicating that the total value to the UK of research to eliminate all uncertainty can be estimated at £279,559,484.

Conclusions

Despite continued engagement with behaviour change techniques, and modest but clinically meaningful changes in physical activity at 12 months, combining a group-based physical activity intervention designed for implementation in primary care with text messaging and telephone support did not result in sustained changes at 48 months.

Although the findings from the embedded qualitative studies suggested a positive impact on physical activity levels and understanding of diabetes risk, combining a group-based physical activity intervention designed for implementation in primary care with text messaging and telephone support may not be cost-effective over the trial period or over a lifetime.

The increased ownership and adoption of self-monitoring technologies in the wider population during the years PROPELS was running was a contextual influence on participants in all three study arms that should be given consideration. The characteristics of the participants at baseline should also be noted; the majority of the participants recruited were not confirmed to have HbA_{1c} values within the prediabetes range at baseline, and > 50% achieved 150 minutes of moderate to vigorous physical activity, with high levels of physical activity self-efficacy reported at baseline in all arms. These findings may, therefore, be generalisable only to relatively healthy, active participants, and not necessarily to those referred to diabetes prevention programmes within primary care. Nevertheless, this study is consistent with the wider literature in both active adults and those with diagnosed type 2 diabetes, as very few studies have reported sustained increases in objectively assessed physical activity beyond 12 months.

The embedded qualitative research revealed several explanations for the poor sustainability of the physical activity increase found in the trial. Notably, factors related to ageing and associated health risks and conditions featured prominently, with falls, accidents or surgery – and the associated recovery – leading to long periods of reduced activity. This suggests that effectiveness may be enhanced by incorporating additional support designed to improve resilience to such life events that participants can call on in the event of a major health issue/illness.

Future research should, therefore, focus on identifying the intervention types, components and features that are most successful in helping maintain physical activity behaviour change over the long term and in diverse populations; evaluating the long-term effectiveness and cost-effectiveness of routinely delivered national diabetes prevention programmes; testing a stepped prevention programme of initial lifestyle intervention before offering pharmacological interventions (e.g. metformin) to those who do not adhere to or are unable to take up lifestyle interventions; illuminating the importance of risk status and risk communication to behaviour change; and exploring the importance of integrating rehabilitation from illness or injury as a core intervention component to sustain long-term physical activity behaviour change.

Trial registration

This trial is registered as ISRCTN83465245.

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This report

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