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Promoting Physical Activity in the Management of Type 2 Diabetes: A Feasibility Study to Develop Intervention Tools for Delivery of Diabetes-Specific Education

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ABSTRACT

Background: Physical activity is an important aspect of lifestyle management and type 2 diabetes, although the percentage of people with type 2 diabetes achieving recommended guidelines is low. Supported self-management underpinned by group educational programmes may be helpful but difficult to implement in remote and rural areas. We aimed to test the feasibility of an approach based on education delivered individually by community-based exercise advisors to people with type 2 diabetes.

Methods: Following the development of an online educational toolkit a mixture of exercise advisors and people with type 2 diabetes were recruited. People with diabetes had a face-to-face consultation with an exercise advisor with mutually agreed follow-up over 6 months. To track physical activity, people with diabetes aimed to wear an accelerometer device for 7 days at baseline, 3 months and 6 months. Post-intervention semi-structured interviews were undertaken with both groups of participants to gauge perspectives of the initiative.

Results: There was a 56% total attrition rate from baseline to 3 months due to COVID-19 and its impact on clinical research. Around 50% of participants achieved minimum physical activity recommendations at each time point and 22% of participants had accelerometer data at 3 time points. People with diabetes valued interaction with exercise advisors and felt that the programme would be of greatest benefit to less active individuals. Exercise advisors felt that the programme provided more opportunities and increased confidence and that training in working with older less active individuals would be useful for them.

Conclusion: It is feasible to develop a physical activity programme delivered by non-healthcare practitioners underpinned by diabetes-specific education tailored to people with type 2 diabetes. Several project adaptions should be considered for progress to a pilot study to assess an integrated physical activity programme delivered by community exercise advisors.

1 | Introduction

Physical activity (PA) alongside an energy-reduced diet promotes improved glycaemic control in type 2 diabetes (T2D) [1]. Further, regular exercise can improve blood glucose levels independently of weight loss and provides additional benefits through lowering body fat percentage and reducing blood pressure [2]. In the United Kingdom, only about 9% of people living with T2D reach the recommended PA target of 150 min per week necessary to attain cardiovascular benefits [3] with low numbers reported worldwide [4]. It is also evident that the cardiovascular protection associated with PA is greater the earlier after diagnosis of T2D that PA is introduced [5]. Several internal and external barriers to participation in PA have been identified in T2D including psychosocial barriers [6] and concerns about incurring injuries [7] identified as contributing to low levels of participation in PA, and it is suggested that counselling could help to identify barriers and provide support to overcome them [8]. In addition, quality of counselling with regard to lifestyle changes is associated with enhanced behaviour change and motivation to exercise [9]. Evidence suggests that advice should be given to every person living with T2D regardless of stage of change [10].

Advising people to take more exercise is ineffective though brief interventions in primary care may be useful [11]. The feasibility of PA intervention for diabetes has been tested in a clinical setting using a PA consultant where face-to-face consultation was considered helpful [12]. Moreover, one-to-one support for those with low levels of PA at baseline has been demonstrated to produce a significant increase in PA levels [13]. Nevertheless, widespread delivery of specific PA education through specialist or generalist healthcare practitioners is not feasible, especially in geographically challenged areas.

Supported self-management is key to attaining good glycaemic control and education underpins this approach [14]. In the United Kingdom, there are several validated group-based structured education courses designed for people living with T2D, including DESMOND, XPERT and Conversation Maps with varying levels of information on PA and some centre-based structured education courses which address PA education such as PREPARE, modelled on the DESMOND programme [15]. There are challenges in delivering group-based education in the Highland region of Scotland related to the dispersed nature of the population and issues surrounding privacy in rural communities [16].

The limitations described, in conjunction with the increasing prevalence of T2D, suggest that an alternative approach is required to deliver education and support to aid lifestyle changes as recommended in national guideline recommendations for PA to the growing number of people living with T2D in the Highland region [17, 18].

2 | Methods

This was a mixed-methods feasibility study using a co-production model throughout that involved patients, healthcare practitioners, exercise advisors (EA) and researchers.

2.1 | Participants

Participants included people diagnosed with T2D and EA. People with diabetes were recruited from diabetes specialist nurse community clinics, targeted practice nurse-led primary care clinics, local Diabetes Scotland group and self-referral through poster-adverts in GP surgeries, pharmacies and the Highland diabetes centre. Recruitment of volunteers was also done by public advertising using social media and local newsletters. Inclusion criteria were as follows: adults aged between 18 and 75 years, T2D diagnosis of any duration of disease and receiving any form of diabetes therapy. Exclusion criteria were as follows: people with any significant co-morbidities or illness precluding participation in PA and those lacking capacity or unable to consent to participate.

EAs with documented level 3 training in delivery of PA were recruited in response to poster distribution through the High Life Highland (HLH) leisure services management team and contributed in-kind to the study. Training covered nutrition, weight management, physiology, core and functional training and behaviour change. The aim was an initial face-to-face meeting (up to 1 h) with follow-up at 2–3 weeks (either face to face, email or by phone–as agreed between the EA and person with T2D) with any incidental follow-up and support arranged if requested by the patient through email, phone or face-to-face.

Participant information sheets and leaflets were provided and written informed consent was obtained prior to enrolment in the study. The study was conducted according to the principles and agreements of the Helsinki Agreement. The study received ethical approval from the London−Queen Square Research Ethics Committee (reference number: 18/LO/0672).

2.2 | Measurements

Height was measured to the nearest 0.1 cm using a portable stadiometer (model 213, SECA, Hamburg, Germany), and body mass was measured to the nearest 0.1 kg. Baseline subjective and objective PA data were collected, respectively, using the International Physical Activity Questionnaire-Short Form (IPAQ-SF; 19) and the Actigraph wGT3X-BT accelerometer (Actigraph LLC, Pensacola, FL, USA), to be worn for 7 consecutive days during waking hours. The accelerometer was a small lightweight device (4.6 × 3.3 × 1.5 cm; 19 g) worn on a belt around the waist to record step counts, time at rest and time in light, moderate and vigorous PA.

Further accelerometer data and IPAQ responses were collected at 3 months and 6 months. Participants were also provided with a logbook and asked to report if they removed the accelerometer during waking hours, what time of day they removed the accelerometer and reasons for this.

Data from the accelerometer were processed using the ActiLife software (version 6.13.4; Actigraph LLC, Pensacola, FL, USA) in accordance with published guidance [20] and to meet the following criteria: (1) minimum number of valid days required = 3; (2) non-wear-time set at >60 min of consecutive zeros; (3) minimum number of wear hours per day required set at >10 h (600 min). The Freedson [21] cut-off points for adults were used to differentiate activity intensity. Average time (min/day) in moderate to vigorous physical activity (MVPA), light physical activity (LPA) and rest were extracted.

2.3 | Online Toolkit Development

The information toolkit was developed based on enhancement of existing material within a web format [15]. This information created was based on feedback from focus groups of people living with T2D (N = 30) and health professionals (N = 6) working in diabetes, that identified gaps in diabetes-specific exercise advice for people with T2D. The content included general information on frequency, duration and intensity of exercise as well as how to progress this over time in relation to current PA levels and diabetes-related problems. The aim was to use the toolkit as an additional educational resource for both EAs and people with T2D.

Refinement of the toolkit with expansion to include information on exercise in the context of diabetes-related complications was informed by further focus groups comprising representatives from EAs, diabetes healthcare practitioners and people living with T2D. The final version was produced by the university Learning Improvement Service.

2.4 | Exercise Advisor Training

EAs received face-to-face tutorials prior to commencement of the study from healthcare professionals and members of the university 'active health' academic team including a behavioural scientist with expertise in PA in clinical populations. These included background information on diabetes and the role of PA in diabetes management, linked to behaviour change theory. EAs were provided with access to the toolkit and instructions.

2.5 | Intervention

Initial contact between EAs and participants was on a one-to-one basis with or without an accompanying person within local HLH premises normally used for PA. The toolkit was intended to be used with the participant to match personal activity recommendations to the current level of fitness/activity, individual choice and any diabetes-related complications or problems. Information relevant to the PA recommendations was explained to the individual by the EAs. Diabetes specialist nursing staff provided support if assistance was required with any aspect of diabetes therapy during PA.

EAs maintained contact with participants for up to 6 months. This included a scripted review at 2–3 weeks after the initial contact by either face-to-face or telephone call. Thereafter, future contact was determined by participant choice and included face to face, email or telephone. EAs recorded all contacts, including dates, times and nature of interaction and noted activities undertaken according to recommendations from the EAs and any other PA during the 6-month period for all participants assigned to them.

2.6 | Semi-Structured Interviews

Post-study semi-structured interviews were carried out with both groups of participants to examine their views and experiences following the intervention from both perspectives. EAs were asked about their use of the toolkit and to what extent the initial education session had helped them prepare for the delivery of diabetes-specific PA education.

Interviews were conducted by telephone or video call with 11 participants and five EAs. The interviews were semi-structured with the interviewer using follow-up prompts as required within the interview schedule. Participation information sheets and consent forms were sent to interviewees electronically. All interviewees had the opportunity to ask questions prior to the interview. The average length of interviews was 36 min, and these were recorded using an external digital voice recorder. Interview questions focused on positive and negative experiences of the intervention, the impact on knowledge of diabetes management, effect on PA levels, use of the online toolkit, reasons for success or failure, barriers and suggestions for improvement. The interviews were professionally transcribed verbatim and analysed thematically [22].

2.7 | Statistical Analysis

This was a feasibility study to test a new pathway of intervention and the feasibility of utilising an online educational tool therefore no power calculation was performed. Based on experience of similar studies, we proposed to recruit a minimum of 20 individuals with T2D across the HLH areas participating. Non-parametric (Mann–Whitney or Wilcoxon signed-rank as appropriate) tests were carried out to examine differences between groups. Values are expressed as median and interquartile range (IQR).

3 | Results

A total of 41 individuals were assessed as eligible for participation. Thirty-four participants were enrolled of which 18 were male and 16 were female, with 32 completing baseline measures. Seven participants withdrew before having an initial appointment with an EA, and two more failed to complete baseline measures.

Details of participants proceeding to study visits at 3 and 6 months and reasons for attrition are shown in Figure 1. There was a significant fall in numbers between baseline and the 3-month visit due to participants being lost to follow-up or discontinuation when clinical research was halted due to the COVID-19 pandemic.

3.1 | Sample Characteristics

Baseline characteristics for participants with diabetes, including IPAQ responses and Actigraph data, are shown in Table 1.

3.2 | Use of the Toolkit and Participant Contact

While it was anticipated that the toolkit would be used and viewed jointly during at least the first face-to-face meeting between the EAs and participants with diabetes, it was mainly used by the EAs to provide them with background information on T2D and related complications and thus help to inform the tailored advice shared with participants with diabetes.

3.3 | Contacts With EAs

Even though 32 participants completed baseline measures, eight (25%) participants withdrew before they had an initial appoint-

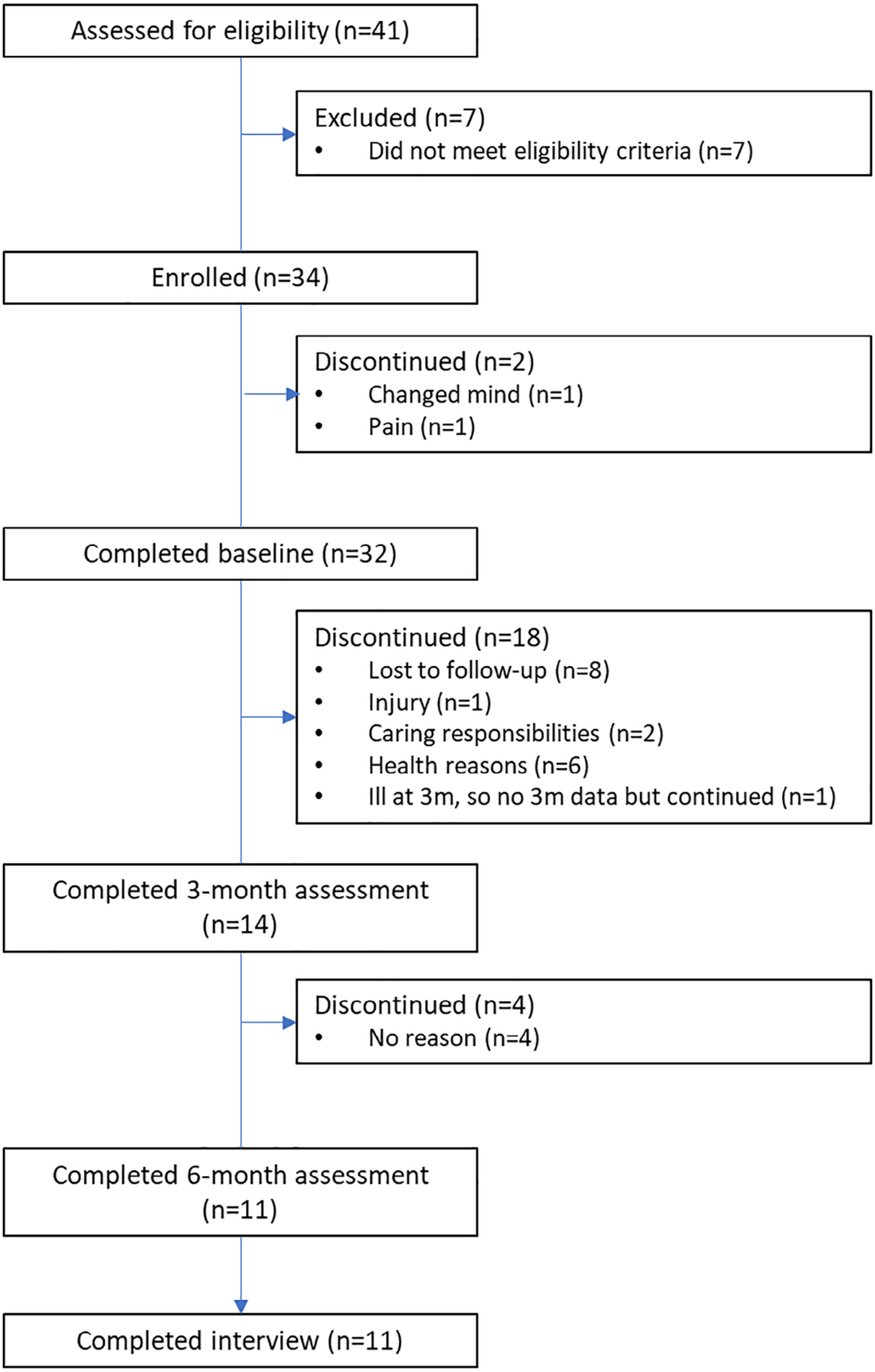

FIGURE 1 | Diagram summarising participant flow showing the number of participants recruited, enrolled, discontinued, completed assessment and included in the analyses are presented. *One patient with no 3-month data completed the 6-month assessment.

ment with an EA (n = 24, 75%). Of these 24 participants, 12 (50%) attended a follow-up appointment 2–3 weeks after the initial appointment.

There were detailed EA notes for 14 of the participants (the notes from one EA [five participants] were lost during a building fire, the notes for the remaining participants were not completed by the EAs). From the detailed notes provided for these 14 participants, eight received further contact beyond the 2–3 weeks follow-up period (median number of further contacts = 2, range 1–21). These contacts occurred by phone, text or email according to participant preference.

TABLE 1 | Baseline characteristics of the group.

	Male (n = 17)	Female (n = 15)	Overall (n = 32)
Age (year)	61 (13.0)	61 (15.0)	61 (13.5)
BMI (kg/m^2)	30.0 (9.6)	35.1 (7.7)	33.6 (8.3)
Physical activity			
IPAQ	N = 15	N = 15	N = 30
Sitting (min/day)	480.0 (270)	360.0 (264)	450 (252)
MVPA (min/day)	17.1 (68.6)	28.6 (48.6)	19.6 (53.6)
Actigraph (min/day)	N = 15	N = 12	N = 27
Sedentary	628.4 (72.0)	562.2 (95.0)	611.4 (105.7)
Light	130.3 (88.0)	188.8 (42.8)	158.2 (86.6)
Moderate	31.1 (31.0)	20.1 (13.5)	25.3 (23.2)
Vigorous	0.3 (0.5)	0.2 (0.3)	0.2 (0.4)

Note: Values are median (IQR).

3.4 | Physical Activity

At any time-point about 50% of individuals who returned an Actigraph with valid data achieved the minimum guideline recommendations of 150 min of MVPA per week (baseline 15/27 [56%]; 3-month 7/12 [58%] and 6-month 4/8[50%]) based on 3 days valid wear time. Only seven participants returned valid Actigraph data at all 3 times points. There was no difference in baseline PA levels (sedentary, light PA or MVPA) between those who returned valid Actigraph data at 3 M and those who did not ($p > 0.05$). Similarly, there was no difference in the baseline PA levels between those who returned valid Actigraph data at 6 months and those who did not ($p > 0.05$). For the 12 participants who returned valid Actigraph data at 3 months, there was no evidence of a change in sedentary or light PA ($p > 0.05$). There was evidence of a small increase in MVPA ($Z = -2.04$, $p = 0.04$). The median MVPA score at baseline was 22.0 min and 25.5 min at 3 months. For the eight participants who returned valid Actigraph data at 6 months, there was no evidence of a change in sedentary, light PA or MVPA (all $p > 0.05$). Figure 2 presents the MVPA for all individuals who returned valid Actigraph data for at least 2 time points. Similar patterns of change were observed in the self-reported MVPA data from the IPAQ (Figure 3).

3.5 | Interviews With Participants

3.5.1 | People With T2D

Two types of participants could be identified. The first group was already physically active, having made lifestyle changes prior to participation in the programme. The second group tended to be less active and wanted support to increase motivation to take up exercise or to increase low levels of current PA.

> I had already made the lifestyle choices and everything that the programme tried to encourage anyway but it was an opportunity just to see what other information was out there to help me get on top of it.

The impact on PA was deemed low to moderate depending on how much they were exercising already. The greatest increase in PA was reported in the less active group of interviewees, who tended to benefit from encouragement, and checking-in, which helped to build confidence and motivation.

> It's given me this get up and go, which I didn't have when ___ first started me on the trial. I just didn't want to exercise, I didn't want to go out and about, I just wanted to be a couch potato whereas now I'm quite happy to go out and about and I've joined the gym and I'm just a happier girl–or woman!

The more active group benefited from personalised advice on specific activities and honing their exercise regimens. They tended to think the programme was more suitable for less active people. Increasing motivation was seen as an important benefit of the programme and a key factor in bringing about lifestyle change. However, results in terms of diabetes management and weight loss were generally attributed to a combination of factors not only the EA programme. Being treated like an individual and having to report on progress were both valued and given as reasons for success.

> I felt that I was being treated as an individual, it wasn't a one-size-fits-all, it was a 'let's see what fits you and what suits you'. And that, I felt, was really, really beneficial.

Generally, it was felt that the EA had more time to dedicate to each person than a healthcare professional. Knowledge of diabetes and PA increased for some, but others felt the programme mainly reinforced what they already knew, although this was also seen as beneficial and positive.

3.5.2 | Exercise Advisors

The online toolkit helped to increase or refresh knowledge and was useful for EAs, particularly the links to other websites and tools.

> [I]t is spot-on, it's outdoorsy with just a nice lady and gentleman out for a walk. It says a lot, it says you don't need to go to gym, you don't have to run and … you can make small changes yourself.

However, it was not widely used over the extended lifetime of the project and EAs saw relatively few participants over a long period. The toolkit was not commonly used directly with patients, who were generally unaware of the toolkit. More information in the toolkit on complications and their impact on PA as well as on nutrition were called for by two EAs. Taking on a range of participants with divergent activity levels may have made it more difficult for EAs to design programmes. This depended on their differing experience and level of qualifications. One EA highlighted that most instructors do not tend to work with older, less active clients but with younger, fitter people.

> Not all personal trainers have necessarily got experience of working with less active older people, a lot of personal trainers work with people who are incredibly fit.

The benefits for EAs included being able to practise their skills, increased confidence and knowledge, working with different types of clients, extending their geographical reach and opening up new opportunities. Suggested improvements included more contact, particularly face to face, with EAs, more regular communication, information on nutrition and greater structure to sessions.

4 | Discussion

There is a need for improved provision and access to options for increasing the uptake of appropriate levels of PA for people living with T2D, pre-diabetes or at risk of developing T2D [23] taking cognisance of the more recent evidence for reducing sedentary time and exercise timing [24]. It is also important that preferences and exercise modalities are considered in conjunction with adverse events and complications [25]. The use of mHealth technology may offer a contribution in this environment; however, further evidence of effectiveness is required [26].

Due to attrition and the final small number of participants completing the study, we were unable to demonstrate a sustained impact of the intervention on PA. However, we have shown that through a co-production process it is possible for non-healthcare practitioners in the form of EAs, to provide input and support to people with T2D wishing to improve their PA levels. This involved the delivery of diabetes-specific education and use of a web-based toolkit aimed at informing optimal tailored PA including information and programme adaption for, diabetes-related complications where they exist, for example retinopathy,

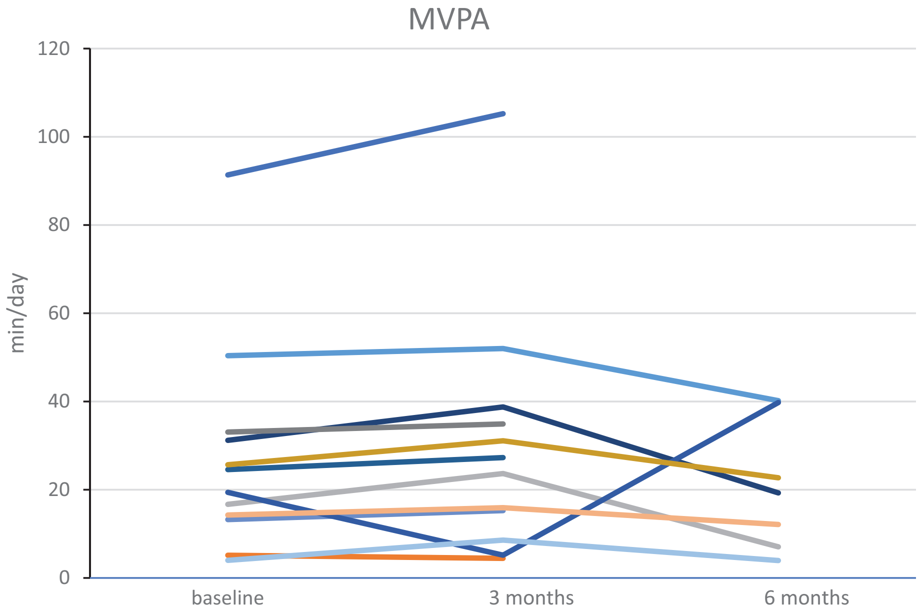

FIGURE 2 | MVPA by time for individual participants who returned valid Actigraph data for at least 2 time points.

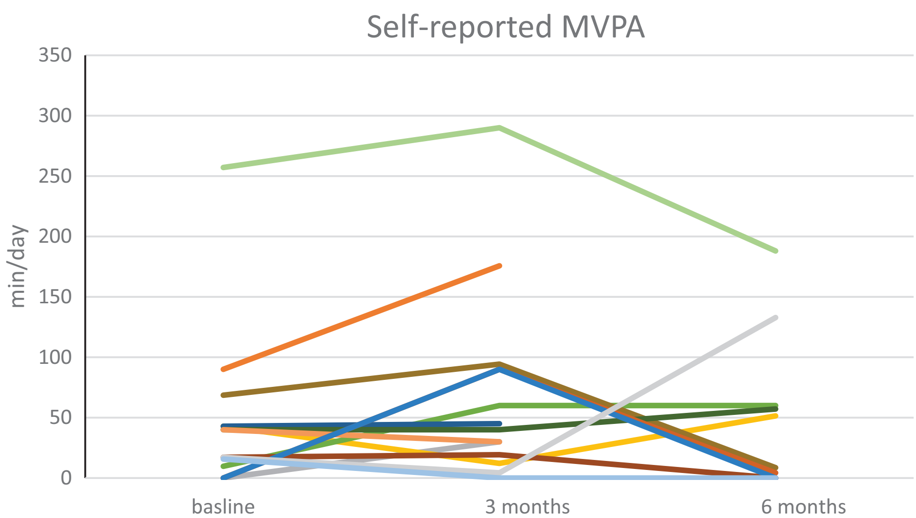

FIGURE 3 | Self-reported MVPA by time for individual participants who returned valid IPAQ data for at least 2 time points.

neuropathy, nephropathy, hypertension and cardiovascular disease.

The toolkit was thought to be useful by EAs but was not employed much throughout the study. It appeared to be used by the EA to assist their own knowledge base and increase confidence, but it was unknown how much it had been employed in conjunction with people with diabetes during initial or subsequent consultations as had been anticipated. Nevertheless, participants with diabetes valued the individualised attention they received from EAs.

Participants with diabetes fell roughly into two groups comprising those already physically active and those less so. The more active group, while more knowledgeable about PA and diabetes still felt the interaction with an EA was beneficial. Unsurprisingly, the greatest increase in self-reported PA was in the least active group at the start of the project. Overall, around 50% of individuals were meeting the recommendations for MVPA of 150 h per week at all 3 time points in the study; however, poor compliance with the Actigraph wear protocol limited our insight into potential changes in MVPA, and compliance would need to be addressed in any future study.

The COVID-19 pandemic had a significant impact on recruitment and retention of people with diabetes to the study due to the implementation of a significant pause in clinical research during this time. As the study restarted, there was a lack of initial face-to-face interaction, dictated by local guidelines, between researchers and participants. Mental health issues were not stated as a health reason for withdrawal from the study at any stage, and participants were not screened for mental health issues specifically. However, we cannot discount the possibility that mental health issues such as depression may have contributed to adherence to the programme [27].

In terms of the study concept, a number of further challenges were highlighted. First, recruitment of sufficient EAs to the project across a wide enough geographical area proved difficult and strategies to ensure wider regional promotion and induction would be necessary to allow equity of access for people with diabetes to EAs in non-healthcare settings if this was to be developed as an integrated service. Moreover, lack of face-to-face meetings between EAs and people with diabetes likely impacted the use and awareness of the education toolkit within the T2D patient group.

Individual exercise training and exercise experience varied amongst the EAs (as highlighted in the interviews). In general, most EAs were not used to working with older less-active individuals with medical conditions and would need support to take this type of programme forward. Evidence from other similar approaches employing non-healthcare professionals is lacking although it is recognised that there is a lack of structure around PA promotion skills in primary care and a need for access to referral routes and key responsible individuals with diabetes-specific information [28].

The Actigraph devices were used to provide quantitative data as an indicator of change in PA compared with self-reported activity for the research team. However, there was low compliance with the wear protocol for these devices leading to substantial missing data. As there is no real-time participant feedback associated with this device, it may be of limited use in an established PA programme. A different device that encouraged behaviour change through motivation would need to be used to provide feedback on PA. The devices used here, however, do provide objective data outputs that would enhance PA assessment with a wider pilot study.

4.1 | Limitations

Recruitment started as face-to-face but changed to email and telephone interaction for both groups of participants when clinical research restarted. It is not clear how this may have impacted recruitment. There was also a high attrition rate of participants with diabetes following baseline assessment and throughout the study, partly related to the pandemic and aftermath restrictions, but a feature that has also been highlighted in PA studies often with similar duration [29]. Rates of attrition are also reported to be high from mHealth interventions [30]. It should also be recognised that all the participants were of white Caucasian origin, and this intervention may not be applicable to different ethnicities in the same setting [31].

4.2 | Recommendations for Future Trials of the Intervention

Several factors should be considered for the effectiveness of the intervention to be assessed in a future trial of the intervention. These include increased sharing and discussion of the toolkit contents with participants to assess its value throughout the intervention; exploration of ways to encourage better compliance with the Actigraph wear protocol; screening for mental health or other issues that may impair adherence to the intervention programme; aim to recruit more EAs and more face-to-face interaction between EAs and participants with diabetes and ensure training of EAs in working with older less active individuals.

5 | Conclusions

This project has demonstrated that it is feasible to develop a PA programme delivered by non-healthcare EAs in a community setting, that is underpinned by diabetes-specific education tailored to the needs of people with T2D and by extension to those with pre-diabetes. We have identified several project adaptions that should be considered to confer a good likelihood that this could progress to a pilot study to inform the possibility of developing a collaborative, integrated PA programme utilised by clinical services and delivered by community EAs associated with community leisure services. There are a multitude of compounding factors, and we cannot comment on the likely effectiveness of the intervention.

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Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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