



Diabetes Digital Coach Challenge: KiActiv[®] Health Evaluation Report

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1 Executive Summary

Physical Activity is acknowledged as possibly the single most important thing to do for people with diabetes^{1,2} and is recommended for people with Type 1 and Type 2 by the National Institute for Health and Care Excellence (NICE)^{3,4}. However, existing interventions, which are largely focused on exercise and sport have failed to engage those most in-need or deliver sustainable behaviour change for quantifiable health benefit.

Advancements in technology have enabled KiActiv[®] to develop and prove a low-cost, scalable digital intervention that overcomes the current failures and facilitates the effective use of Physical Activity as a medicine for a broad range of long-term conditions. Furthermore, our unique, methodology (patent pending) allows us to utilise accurate data from validated wearable devices to comprehensively evaluate physical activity in the context of health and significantly enhance the understanding of its financial impact within the NHS.

KiActiv[®] Health is an interactive digital behavioural change platform that uses personalised Everyday Physical Activity in multiple dimensions for the prevention and treatment of chronic disease. It delivers engagement, motivation and understanding to the individual, empowering personal responsibility and self-management. KiActiv[®] Health is based on established behavioural science and the evidence from the Mi-PACT Study with the University of Bath, which proved KiActiv[®] to be effective at delivering meaningful and sustainable behaviour change for physical activity. The interactive tools and visualisations give the user an understanding of their own Physical Activity, and show the impact of possible lifestyle changes, enabling authentic choice to support self-endorsed change (Figure 1).



Figure 1. KiActiv[®] Health Programme

This Challenge provided the opportunity to demonstrate the effectiveness of KiActiv[®] Health, as a Digital Behaviour Change Programme for improving Diabetes self-management by empowering a sustainable increase in Everyday Physical Activity levels.

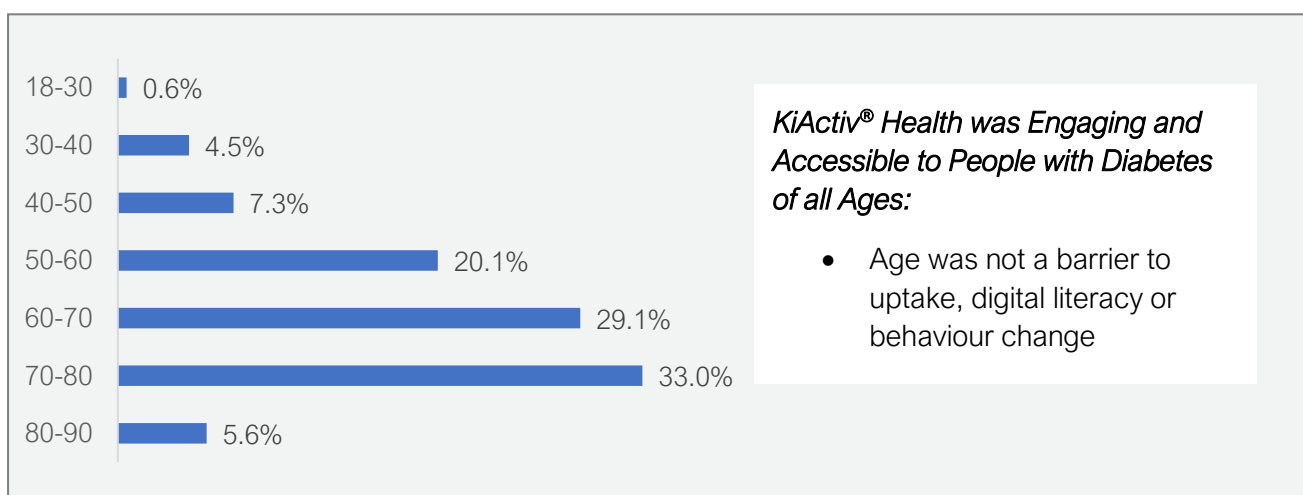
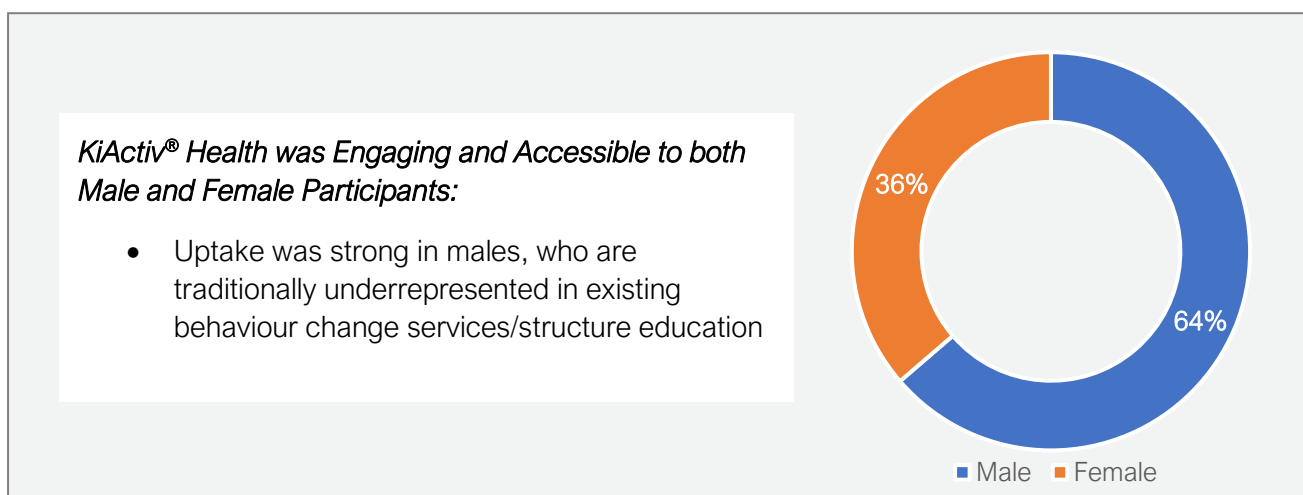
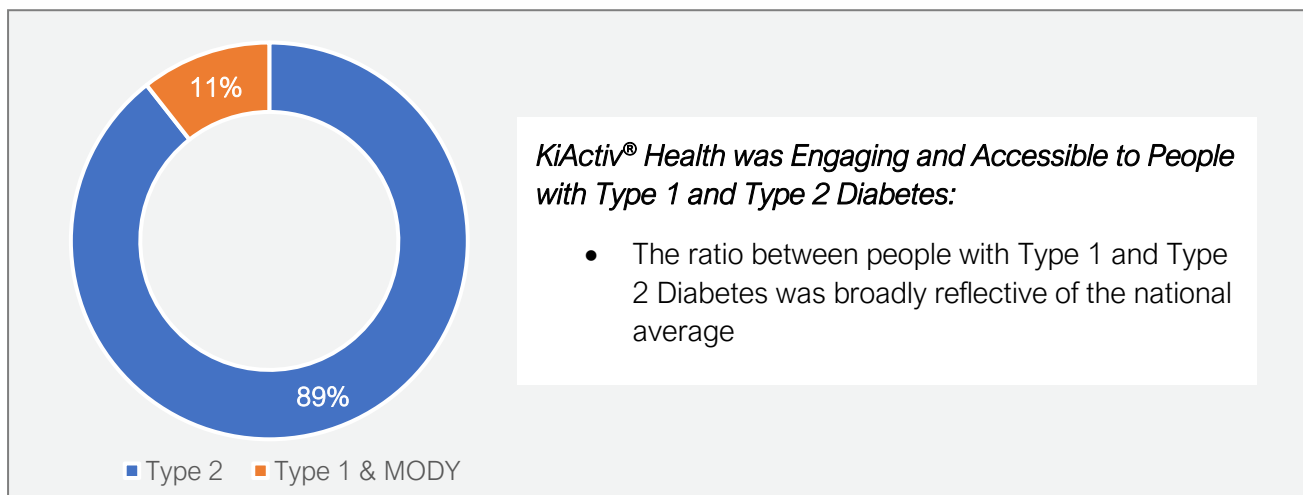
The Challenge was supported and funded by the West of England Academic Health Science Network, who held a rigorous and competitive selection process prior to matching KiActiv[®] with NHS Gloucestershire Clinical Commissioning Group. Working with the CCG, three Primary Care Practices were identified, which provided different demographics and levels of deprivation, to demonstrate scalability and replicability across the health economy.

The Practices were only required to identify and invite eligible patients to join the programme, and this minimal workload enabled a seamless adoption. The invitation letters sent by the Practices

were co-designed with clinicians, commissioners and patients to optimise recruitment and engage people with Diabetes in their own self-care.

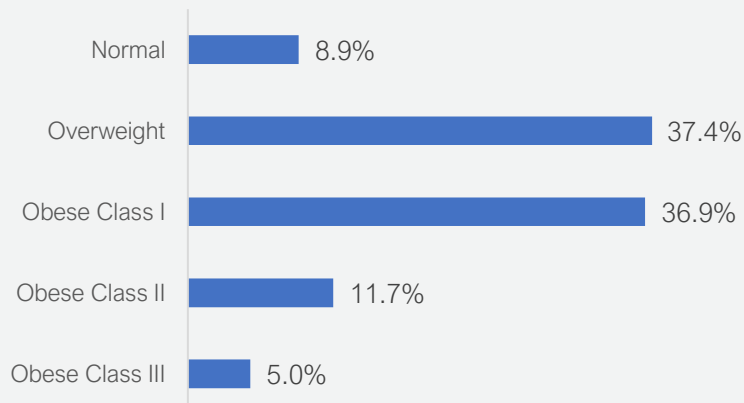
Two hundred and twenty-eight people with Diabetes contacted Ki regarding the programme, of which only 5 did not want to enrol. Forty-four were subsequently screened out due to ineligibility and 179 started the KiActiv® Health programme.

Demographic Analysis Highlighted the Following Key Points:



The use of Everyday Physical Activity was Engaging and Accessible to People with Diabetes across the BMI spectrum:

- The emphasis on sport and exercise in traditional interventions is often a barrier to uptake for overweight and obese individuals



Over 97% of patients increased their Physical Activity, with 83.9% improving in 4 or more dimensions; sedentary time, moderate activity, calorie burn, moderate bouts, and vigorous bouts. In each of the dimensions of Physical Activity, improvements were demonstrated to be statistically significant. These levels of Physical Activity behaviour change are all the more remarkable when looked at in the demographic context, and in particular highlights the opportunities for its use within healthy ageing, falls and frailty prevention, and other long-term conditions.

The increases in Physical Activity were further supported by patients' qualitative feedback, which demonstrated an improved understanding of their Physical Activity and greater confidence in the ability to manage it for their Diabetes and wider health benefit. Furthermore, as a result of their increases in Physical Activity, patients reported experiencing a number of other benefits, which are tied to improvements in quality of life. These include:

- Weight loss
- Reductions in pain
- Reductions in medications
- Improvements in mobility
- Reductions in fatigue
- Improved mood



Ian Mean
70 years of age
Type 2 Diabetes
Hucclecote Surgery

Patient Testimonial

"It has given me a better awareness of the need to exercise in every possible way throughout the day to increase body activity with the result that my overnight blood glucose sugar level in the morning on waking is averaging 7.5 whereas previously it was getting up to 13.00. My understanding of diabetes, the importance of body activity and eating sensibly has helped me to now keep recording consistently low blood glucose levels which I had not been able to achieve previously."

Our method of objectively and comprehensively evaluating Physical Activity in its totality enables us to demonstrate clinical impact through the existing scientific evidence base. Indeed, weight loss is often used as a clinical surrogate and, through our robust methodology, physical activity can now be used in the same way. As such, the group achieved Physical Activity levels that are shown to reduce HbA_{1c} by 0.9%, which is associated with a risk reduction of 32.9% for microvascular complications. In addition, the Physical Activity behaviour can be linked to the improved management or reduced risk of co-morbidities such as Heart Disease, Stroke, Dementia, Depression and certain Cancers^{5,6,7}.

Importantly, we are able to model the economic benefit of the positive behaviour change achieved, accounting for the improved health outcomes, reductions in future costs associated with medicines, microvascular complications, and co-morbidities, and productivity gains. Whilst this analysis is not comprehensive, because a number of health benefits from physical activity are unaccounted for, we are able to demonstrate a positive return on investment within a 1-year, 5-year and 10-year time horizon (Figure 2).



Figure 2. 1-year, 5-year and 10-year return on investment.

KiActiv[®] Health effectively empowered people with Diabetes to improve the self-management of their condition using Everyday Physical Activity, which met the desire to reduce their reliance on healthcare professionals. Despite the age demographics and high incidence of co-morbidities the emphasis on Everyday Physical Activity proved accessible and engaging, allowing participants to change in a way that was most appropriate to them, achieving health benefits despite their own personal challenges. Patient demographics highlighted that KiActiv[®] Health was accessible and engaging, for both men and women of all ages across the deprivation scale. These findings demonstrate the programmes' positive impact on inequalities and highlight the opportunity to widen the use of Physical Activity as a Medicine within Primary Care.

The results also present the opportunity to use Everyday Physical Activity as a Medicine to support the transition from condition specific pathways to a more holistic patient centric service. Measurable health benefit can be demonstrated across multiple mental and physical health pathways, and as such provides a cost-effective intervention to improve self-care and personal responsibility in line with the Five Year Forward View⁸.

A spend-to-save business case, driven by the remarkable improvements in physical activity and associated health benefits, has been successfully submitted to NHS Gloucestershire CCG, and as a result KiActiv[®] Health will be offered to a further 500 people with Diabetes across Gloucestershire. Recruitment will focus on people with Type 2 Diabetes, identified from the GP Practices with higher levels of deprivation.

2 Introduction

2.1 Rationale for the intervention

Physical Activity is a recommended intervention under the NICE guidelines^{3,4} for people with Type 1 and Type 2 diabetes: Physical Activity is fundamental to the treatment of Type 2 Diabetes and should be prescribed by a healthcare professional at initial diagnosis, prior to medications⁹, and continue throughout the management of the condition^{10,11}.

The physiological effects of Physical Activity in Type 2 Diabetes are well established and deliver a statistically and clinically significant beneficial effect on the metabolic state¹² and glycaemic control¹³, improving glucose uptake and insulin sensitivity^{14,15}. Meta-analyses have further concluded that Physical Activity can lower concentrations of glycated haemoglobin A_{1c} (HbA_{1c}) by 0.6-0.9%^{16,17,18,19}. This decrease is similar to that observed with commonly prescribed medications, but without the documented side-effects and expense⁹. However, due to the nature of the evidence being limited to the impact of a single dimension of Physical Activity and focused on exercise rather than the totality of everyday behaviours, this may underestimate the potential impact of Everyday Physical Activity on HbA_{1c} reductions. Furthermore, the benefits of Physical Activity are far reaching, having an additional impact on the prevention of many of the microvascular and neuropathic complications associated with Type 2 Diabetes, and the reduction in risk of multiple chronic conditions such as Coronary Heart Disease, Stroke, Dementia and certain Cancers^{5,6,7}.

2.2 Physical Activity interventions currently offered to patients with Diabetes

Whilst the health benefits of Physical Activity are well established, challenges remain for its effective integration into routine healthcare. The existing Physical Activity interventions in healthcare are largely ineffective and do not deliver improvements in patient outcomes or value for money. They are in the main currently limited to exercise on referral at local leisure facilities, and this approach has exhibited poor take up, retention and completion rates for these programmes. The emphasis on structured exercise has limited patient access and the focus on prescription, compulsion or payment has delivered little evidence of creating sustained behaviour change for Physical Activity. The continued reliance on the narrative of sport and fitness industries has failed to engage those most at-risk or inspire behaviour change. Furthermore, the evidence relating to current Physical Activity interventions is based on inaccurate metrics such as self-report, which renders programme evaluation unreliable and impossible to map onto health outcomes.

Diabetes patients typically spend 3 hours per year with a healthcare practitioner, thereby self-managing for the remaining 8,757 hours²⁰. Enhancing effective self-care with personalised information for the best health choices at the right time is a key focus of the Five Year Forward View⁸.

2.3 Meeting the challenge of making Physical Activity a more effective medicine for improved health outcomes

To overcome the ineffective use of Physical Activity for health, KiActiv[®] set out to deliver an accessible and personalised service for Physical Activity in the context of Diabetes management that in particular addressed the failure to engage with those most in need. We harnessed the latest digital technology and behavioural change science to promote a holistic view of Physical Activity, taking into account incidental daily activity as well as exercise sessions, which individuals would not normally consider to be benefitting their health. The use of personalised Everyday Physical Activity in multiple dimensions improves engagement and accessibility and takes away

the fear or apprehension individuals may have around exercise to empower self-care and sustained health improvement.

2.3.1 Enabling every individual to self-manage behaviour change in their own way

KiActiv® Health is a 12-week evidence-based digital behaviour change programme supported by a personal mentor that is designed to inspire confidence to change and enable patients to take personal responsibility for their condition, by giving them the motivation and understanding to make authentic, self-endorsed lifestyle change. This approach creates a flexible service that moves healthcare beyond its traditional settings and into the community.

2.3.2 Providing a proven evidence-based solution at a time, place and pace to suit the needs of the individual

KiActiv® provides contextualised data feedback to promote an understanding of personal Physical Activity, which is integral to various scientific models of behaviour change and regulation. The social marketing of personalised Physical Activity profiles is a key step towards greater self-empowerment (or self-determined engagement) via the support of autonomy and competence. Research has shown that when individuals experience autonomy and competence in their treatment, they experience volitional engagement and demonstrate greater maintenance of desirable health behaviours²¹.

The multi-dimensional Physical Activity profile offers enormous personalisation and marketing potential in contrast to unidimensional measures of Physical Activity. By providing a profile, there is an opportunity to differentiate, educate and agree personalised goals, self-monitor, reflect, adapt and deal with setbacks. Participants who have low Physical Activity in both guidelines have the most 'choice' and options to engage. Participants who score well in a given dimension are offered opportunities to add to their existing behaviour, knowing that what they are doing is recognised. This approach is bespoke and offers the opportunity to overcome particular or specific barriers. Further, social marketing has succeeded in changing behaviour in a variety of difficult situations^{22,23}.

2.3.3 A person-centric, personalised service supported by a mentor

The mentor supports the individual to develop a personalised Physical Activity strategy in the context of their existing behaviour to achieve the guidelines for their specific disease-state, e.g. to manage their Type 2 Diabetes. This must be led by the user (patient) and will inevitably be highly individualised. Support provided by the Mentor is tailored to the individual (i.e. context-specific guidance such as Physical Activity for weight loss) and this advice is more likely to be perceived as being personally relevant and meaningful, thus supporting sustained behaviour change.

2.3.4 Remote monitoring capabilities for healthcare professionals

KiActiv®'s data driven digital interventions enable authorised healthcare professionals, e.g. the individual's GP etc. to access and review their patient's adherence to the programme, behaviour change and Physical Activity data 24/7.

2.3.5 Objective data provides evidence for the effective evaluation of Everyday Physical Activity as a Medicine for improving the management of Diabetes

Using the latest technology and a digital approach to promoting everyday Physical Activity in multi dimensions delivers the clear opportunity to accurately evaluate behaviour change in the context

of health. It further provides the basis for effectively measuring its impact on health improvement and thereby the associated ROI.

3 Aims and Objectives

We aimed to empower more effective self-management of Diabetes by using technology to provide a personalised understanding of Everyday Physical Activity and how to optimise these everyday behaviours for improved health and wellbeing outcomes.

This project had the following objectives:

1. To evaluate the benefits of KiActiv® Health for improving Physical Activity in people with Diabetes
2. To examine compliance to KiActiv® Health
3. To gain qualitative feedback from participants

The primary outcome was Physical Activity, which was directly and continuously assessed using validated Physical Activity monitors throughout the 12-week programme. Secondary outcomes were compliance to the KiActiv® Health Programme and participant experience.

4 The KiActiv® Health Programme

KiActiv® Health is an interactive digital behavioural change platform that uses personalised Everyday Physical Activity for the prevention and treatment of chronic disease. It delivers engagement, motivation and understanding to the individual, empowering personal responsibility and self-management. The platform expertly evaluates personalised Physical Activity data from an accurate on-body monitor and delivers instant feedback in the context of the user's health. The interactive tools and visualisations give the user an understanding of their own Physical Activity, and show the impact of possible lifestyle changes, enabling authentic choice to support self-endorsed change (Figure 3).

KiActiv® Health is based on established behavioural science and the evidence from the Mi-PACT Study with the University of Bath, which proved KiActiv® to be effective at delivering meaningful and sustainable behaviour change for Physical Activity. The multi-dimensional Physical Activity profiles visualised in the KiActiv® system, created with patients and healthcare professionals, are proven to be easily understood, enhance knowledge of Physical Activity and inspire confidence to change and self-manage²⁴. To support this behaviour change, our system is grounded in Self-Determination Theory, a motivational theory which has strong empirical support in the context of health^{25,26}, including in the context of Physical Activity^{27,28,29}.



Figure 3. KiActiv® Health Programme

5 Methods

5.1 Programme selection process

KiActiv® Health was selected by the West of England Academic Health Sciences Network (WEAHSN) to join the *Diabetes: mHealth – self-management in a digital world* project based on a competitive application process. Submissions were invited from small and medium sized enterprises (SMEs) and third sector organisations whose programmes would ultimately be capable of supplying the NHS with their product or service on a commercial basis in response to the challenge to help people manage their diabetes. The products were required to be already on the market and suitable for people who have more than one long term health condition.

5.2 Engagement with stakeholders

5.2.1 Patient and healthcare practitioner contribution to the KiActiv® platform design

During the development phase of the KiActiv® programme both healthcare practitioners and patients were involved with its co-design. In order for the digital behaviour change platform to be successful, it was vitally important that both groups could understand the visualisations and that this enhanced knowledge of personal Everyday Physical Activity²⁴.

5.2.2 Stakeholder contributions to the pilot project delivery

The WEAHSN was responsible for matching Diabetes Digital Coach SMEs with their member organisations. Working with NHS Gloucestershire Clinical Commissioning Group (CCG) we engaged with GP practices to ensure the management and clinicians understood and supported the programme. Once the Practices were identified, we visited them to introduce the technology and agree the patient invitation letter. Other than identifying patients and sending invitation letters, the requirements on the GP practice were minimal, which meant the programme could be adopted seamlessly.

The successful delivery and positive behaviour change outcomes demonstrated at the initial GP practice led to its spread to two further GP practices in Gloucestershire. We sought to work with Primary Care Practices, with different demographics and deprivation scores, to demonstrate scalability and replicability across the health economy.

5.3 Identification of Potential Participants

Three GP surgeries (Hucclecote Surgery, Hilary Cottage Surgery and The Lydney Practice) participated.

As shown in Figure 4, eligible patients were referred by either the GP or Diabetic Nurse, or by targeting those identified with diabetes from the GP Surgery records. All patient identification and record searching were conducted by the patient's existing care team (Diabetic nurses and administrators in the GP Surgery) who also sent invitation letters to eligible patients (Appendix 1).

Eligible participants were provided with written information about the pilot by post and online at diabetes.kiactiv.com. The recruitment information emphasised that participation was entirely voluntary and that participants were free to withdraw at any time without any impact on their health care or their relationship with Ki or with NHS staff.

Patients made contact with Ki by telephone or email to express an interest and ask questions about the KiActiv® Health programme, confirm whether or not they wish to enrol on the

programme (verbal consent), and to schedule the week 1 and week 2 meetings with the KiActiv® Mentor.

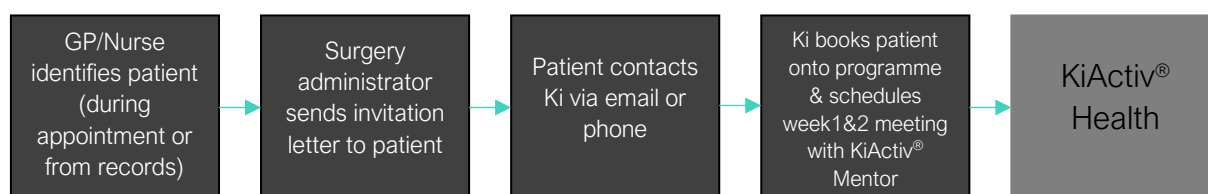


Figure 4. KiActiv® Health referral and recruitment journey

5.3.1 Inclusion criteria

- Able to give informed consent to participate in the pilot
- Registered patient with one of the nominated GP Surgeries
- Male and female
- Any ethnicity
- Aged 18-years or older
- Diagnosed with Type 1 or Type 2 Diabetes mellitus (any time since diagnosis)
- Living at home and able to self-manage their Physical Activity
- Have access to a PC or tablet with internet connection to view the KiActiv® online platform
- Have access to a compatible Smartphone or tablet with internet connection to upload data from the activity monitor

5.3.2 Exclusion criteria

- Individuals unable to change their Physical Activity (e.g. through disability)
- Individuals who already lead highly physically active lifestyles (identified from their baseline multidimensional Physical Activity profile at week 2 meeting with KiActiv® Mentor)

5.4 Delivery Mechanism and content

Participants were asked to attend 6, one-to-one sessions with the KiActiv® Mentor over the 12-week intervention; sessions 1 and 2 (weeks 1 and 2) were conducted face-to-face, for sessions 3, 4, 5, and 6 (weeks 4, 6, 8, and 12) were delivered remotely by telephone. In the first session, participants were given a validated Physical Activity monitor, which was worn on the wrist throughout the 12-week intervention, and the KiActiv® app, used to upload the Physical Activity data, was downloaded to their compatible Smartphone or tablet. In the second meeting, participants were provided with their baseline personalised Physical Activity profile. Subsequent sessions included discussion of progress and guidance of self-monitoring plus personalised social marketing of their Physical Activity profile. Each session was approximately 20-minutes in duration (Figure 5).

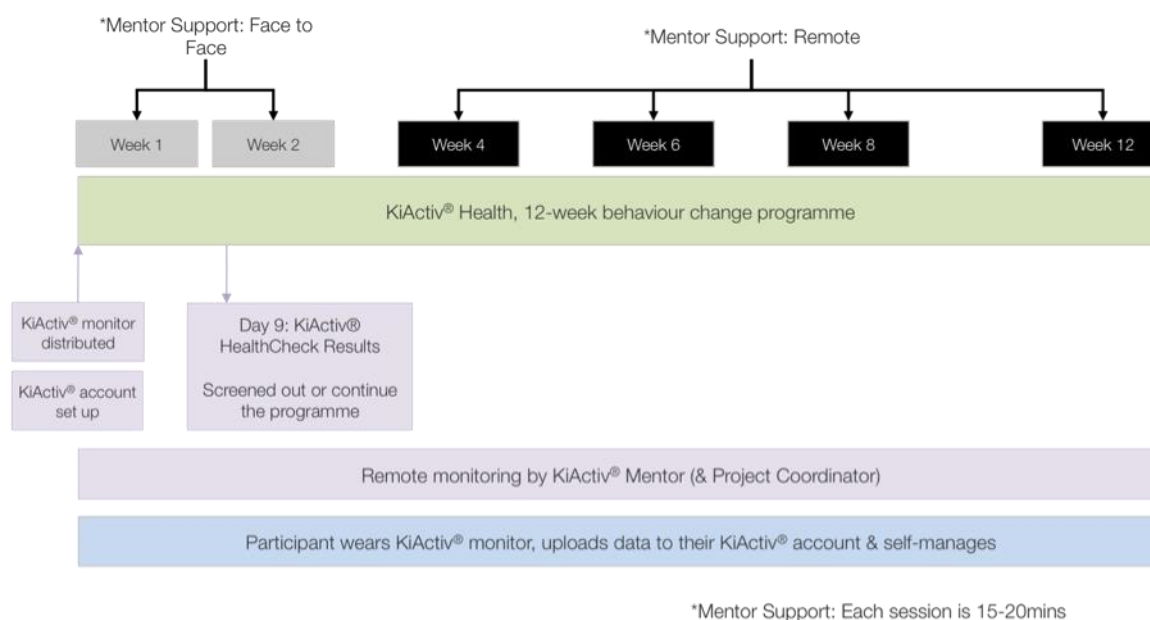


Figure 5. KiActiv® Health timescale

The primary aim of the sessions is to guide participants in navigating the digital platform to optimise the value of its interactive features, which highlight the multidimensional nature of Physical Activity, provide an understanding of which personalised behaviours have contributed to each dimension, and to explain the options and choices available. Consistent with many behaviour change interventions and informed by the work undertaken by our partners at the University of Bath^{24,30} each session has a different emphasis and involves an element of progression (but with significant overlap and the flexibility for the rate of progression to be tailored to the individual).

5.5 Patient Consent Mechanism

At the point that consent was obtained, the patient had had the relevant information and time to discuss the information with family, friends and their healthcare professional. There was an opportunity to discuss any remaining questions they may have had with a member of the Ki team prior to providing verbal consent during the enrolment phone call. Once verbal consent was given, the patient was enrolled into the pilot and the week 1 and 2 meetings with the KiActiv® Mentor were scheduled. Written informed consent was taken by the KiActiv® Mentor during the first face-to-face meeting in week 1. A copy of the signed Informed Consent was given to the participant to keep.

5.6 Equipment and Resources Required

The following equipment and resources were required for the KiActiv® Health pilot.

5.6.1 Recruitment and enrolment

- GP Surgery staff time (e.g. for participant referral by GP/Diabetic Nurse and identification through patient records search conducted by the patient's existing care team [Diabetic nurses and administrators in the GP Surgery], distribution of invitation letter).
- Written communications to provide information to eligible patients about KiActiv® Health (e.g. paper, printer, printer ink, envelope, postage stamps)
- KiActiv® Health for Diabetes information website (diabetes.kiactiv.com)

5.6.2 KiActiv® programme delivery

- Appropriately qualified KiActiv® Mentor (i.e. individual who meets the required competencies and has completed the KiActiv® Mentor Training)
- Meeting Location for face-to-face meetings in weeks 1 and 2 of KiActiv® Health
- Stadiometer and weighing scales (week 1 of KiActiv® Health only)
- Validated Physical Activity monitor (one per participant active on the pilot, e.g. 50 activity monitors would be required to deliver KiActiv® Health to 4 cohorts of 50 participants in a 12-month period)
- Computer with required software for KiActiv® Mentor (provided to KiActiv® Mentor by Ki Performance Lifestyle Ltd.)
- Telephone for KiActiv® Mentor (provided to KiActiv® Mentor by Ki Performance Lifestyle Ltd.)
- To be eligible, participants require access to a PC or Tablet with internet connection to view the KiActiv® online platform and access to a compatible Smartphone or Tablet with internet connection to upload data from the activity monitor.

5.7 Core staff competencies and training requirements

The KiActiv® Health Digital Platform is unique in delivering powerful analysis and interpretation of Everyday Physical Activity data in multiple dimensions to provide top quality coaching with limited resource. The programme replaces subjective opinion with accurate, data driven insights, making it safe, consistent and effective. This places an emphasis on the Mentors' ability to learn the software, motivate and empathise with users and negates the need for high levels of technical qualification. KiActiv® Mentors are required to demonstrate good communication skills, empathy, the ability to motivate, and objectivity.

The KiActiv® Mentor was required to have successfully completed both the Training and Accreditation components of the KiActiv® Health Training programme (i.e. 2 sessions, 1 week apart).

Training involves an explanation of the intervention and the multidimensional nature of Physical Activity; instruction on the use of activity monitors and the KiActiv® Health platform, and discussion of how to use the information provided in the personalised Physical Activity profiles to educate and offer increased choice to participants, before 'listening' and agreeing personalised behaviour goals.

Accreditation involved being observed and assessed delivering a mock KiActiv® Health session.

5.8 Data Collection and evaluation

Evaluation criteria were agreed with NHS Gloucestershire CCG, combining quantitative and qualitative approaches to demonstrating success against our goals.

5.8.1 Quantitative Metrics collected for the KiActiv® Health pilot study

5.8.1.1 Objectively Measured Physical Activity:

Physical Activity was directly and continuously assessed using a validated activity monitor throughout KiActiv® Health. In order to comprehensively evaluate Physical Activity in the context of health, we measured Physical Activity in multiple dimensions (Figure 6), each of which is independently important. Behaviour change was assessed from a blind baseline during the first week of the programme.

Sedentary Time: the amount of time you spend being sedentary (e.g. sitting or lying down).

Moderate Activity: anything that makes you burn 3 times the number of calories you burn at rest.

Calorie Burn: the total number of calories you burn in full 24-hour day from midnight to midnight.

Moderate Bouts: moderate intensity activity performed in sustained bouts of 10-minutes or longer.

Vigorous Bouts: vigorous intensity activity (6 times your resting calorie burn) performed in sustained bouts of 10-minutes or longer.

Figure 6. The multiple dimensions of Physical Activity measured.

5.8.2 Qualitative Metrics collected for the KiActiv® Health pilot study

5.8.2.1 Patient experience:

Patient experience was collected using:

- A self-administered evaluation questionnaire following completion of the KiActiv® Health programme
- Contemporaneous notes taken by the KiActiv® Mentor during each patient contact
- Patient Testimonials

5.8.3 Analysis approach

The following analyses were conducted based on quantitative data extracted as part of this pilot programme:

Descriptive analyses:

- Participant characteristics (age, gender and diabetes type)
- Clinical indicators (weight and BMI) before and after participation
- Compliance to the KiActiv® Programme

Inferential analyses:

- Dependent sample t-test to determine whether there was a significant change in Physical Activity and clinical indicators.
- The Wilcoxon Signed-rank test was used where the assumption of normality was not met.
- The significance threshold was set at 0.05.

6 Results and Discussion

6.1 Patient population

6.1.1 Referral and recruitment

Of the 228 patients who contacted Ki after receiving the invitation letter, 223 were recruited (97.8%). Forty-four were subsequently screened out due to ineligibility and 179 started the KiActiv® Health programme (Figure 7).

Completion rate was 92.7% (166 of 179 patients). All 179 patients who enrolled attended their first session with their KiActiv® Mentor and completed the KiActiv® HealthCheck, and nine (5.0%) completed their programme at this stage. 170 (95.0%) patients continued on to the 11-week behaviour change programme. 19 (10.6%) subsequently ended their programme before the end

of 11 weeks. One patient did not meet the minimum wear time threshold, thus of the 138 patients who completed the 11-week behaviour change programme, 137 contributed to the Physical Activity behaviour change outcome.

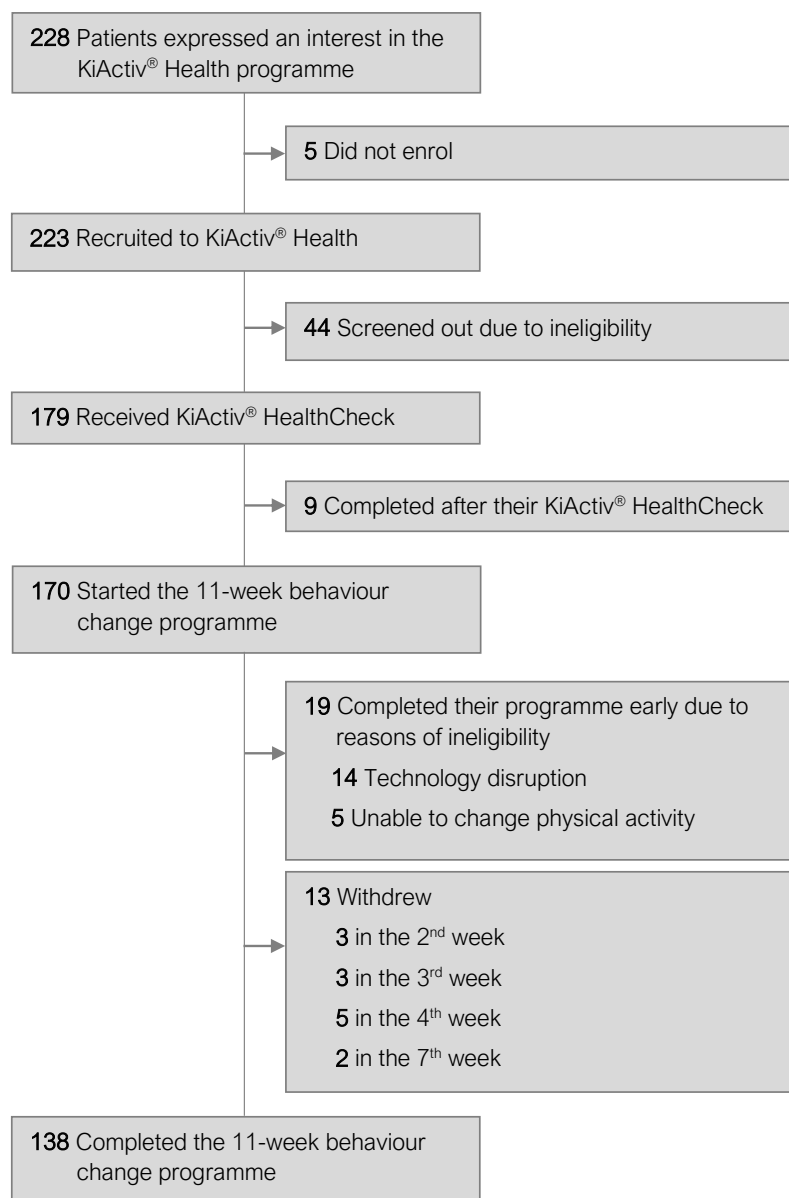


Figure 7. KiActiv® Health programme participation rates

6.1.2 Patient characteristics

Of the 179 patients who enrolled on the KiActiv® Health programme, the mean (SD) age was 63.9 (11.9) years, 160 (89.4%) had Type 2 Diabetes and 114 (63.7%) were men (Table 1). Baseline characteristics of the 138 patients who completed the 11-week behaviour change programme are shown in Table 2 and are similar to those who did not undertake all 12-weeks of the KiActiv® Health programme. The mean (SD) age of this group was 63.3 (11.7) years, 125 (90.6%) had Type 2 diabetes and 88 (63.8%) were men.

	Hucclecote1 n= 41		Hucclecote2 n= 52		Hilary Cottage n= 45		Lydney n= 41		All N= 179		
<i>Gender</i>											
Male	27	66%	38	73%	28	62%	21	51%	114	64%	
Female	14	34%	14	27%	17	38%	20	49%	65	36%	
<i>Diabetes Type</i>											
Type 2 Diabetes	37	90%	49	94%	37	82%	37	90%	160	89%	
Type 1 Diabetes & MODY	4	10%	3	6%	8	18%	4	10%	19	11%	
<i>Age (yrs)</i>											
	55		68		65		66		64		
18-30	0	0%	0	0%	1	2%	0	0%	1	1%	
30-40	5	12%	0	0%	2	4%	1	2%	8	4%	
40-50	7	17%	1	2%	3	7%	2	5%	13	7%	
50-60	16	39%	3	6%	9	20%	8	20%	36	20%	
60-70	9	22%	21	40%	8	18%	14	34%	52	29%	
70-80	4	10%	26	50%	18	40%	11	27%	59	33%	
80-90	0	0%	1	2%	4	9%	5	12%	10	6%	
<i>Height (m)</i>	1.72		1.70		1.69		1.68		1.70		
<i>Weight (kg)</i>	90.48		89.60		84.39		88.40		88.22		
<i>BMI</i>	30.55		30.86		29.63		31.52		30.63		
Underweight	0	0%	0	0%	0	0%	0	0%	0	0%	
Normal	4	10%	3	6%	5	11%	4	10%	16	9%	
Overweight	13	32%	21	40%	19	42%	14	34%	67	37%	
Obese Class I	18	44%	19	37%	17	38%	12	29%	66	37%	
Obese Class II	5	12%	5	10%	4	9%	0	0%	14	8%	
Obese Class III	1	2%	4	8%	0	0%	4	10%	9	5%	

	Hucclecote1 n= 34		Hucclecote2 n= 32		Hilary Cottage n= 34		Lydney n= 38		All N= 138		
<i>Gender</i>											
Male	22	65%	26	81%	21	62%	19	50%	88	64%	
Female	12	35%	6	19%	13	38%	19	50%	50	36%	
<i>Diabetes Type</i>											
Type 2 Diabetes	31	91%	30	94%	30	88%	34	89%	125	91%	
Type 1 Diabetes & MODY	3	9%	2	6%	4	12%	4	11%	13	9%	
<i>Age (yrs)</i>											
	54		68		65		66		63		
18-30	0	0%	0	0%	0	0%	0	0%	0	0%	
30-40	3	9%	0	0%	1	3%	1	3%	5	4%	
40-50	7	21%	1	3%	3	9%	2	5%	13	9%	
50-60	16	47%	1	3%	8	24%	8	21%	33	24%	
60-70	7	21%	12	38%	6	18%	13	34%	38	28%	
70-80	1	3%	17	53%	13	38%	9	24%	40	29%	
80-90	0	0%	1	3%	3	9%	5	13%	9	7%	
<i>Height (m)</i>	1.71		1.71		1.69		1.68		1.70		
<i>Weight (kg)</i>	87.05		92.70		84.89		87.90		88.06		
<i>BMI</i>	29.76		31.57		29.67		31.24		30.56		
Underweight	0	0%	0	0%	0	0%	0	0%	0	0%	
Normal	4	12%	2	6%	3	9%	4	11%	13	9%	
Overweight	11	32%	11	34%	16	47%	13	34%	51	37%	
Obese Class I	16	47%	12	38%	12	35%	12	32%	52	38%	
Obese Class II	3	9%	4	13%	3	9%	6	16%	16	12%	
Obese Class III	0	0%	3	9%	0	0%	3	8%	6	4%	

6.2 Engagement

The number of monitor-wearing days, complete monitor-wearing days, daily average wear times, and sessions attended for those completing the 11-week behaviour change programme are summarised in Table 3.

	Hucclecote1	Hucclecote2	Hilary	Lydney	All
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
<i>Band adherence</i>					
Days Band worn, %	85.6 (20.4)	89.7 (16.9)	92.4 (13.0)	85.1 (22.4)	88.1 (18.7)
Complete days, %	84.8 (12.7)	89.5 (11.5)	92.9 (9.0)	90.9 (9.5)	89.6 (11.0)
Average daily wear time, mins	1099.0 (207.2)	1167.9 (226.6)	1196.4 (223.3)	1256.4 (148.0)	1182.3 (207.9)
<i>Session adherence</i>					
Sessions attended	5.4 (1.0)	5.4 (0.9)	5.1 (1.4)	5.1 (1.2)	5.3 (1.2)

Most of these patients wore the activity monitor over 90% of the programme days (the 25th, median and 75th percentiles are 84.5%, 92.9% and 100% of programme days). The wearing adherence to the minimum wear time protocol was also high (the 25th, median and 75th percentiles are 86.6%, 92.8% and 96.1% of days worn).

The daily average wear time for the activity monitor was 1182.3 (82.1%) minutes of the 1440 minutes in a day (the 25th, median and 75th percentiles are 1087.5, 1261.3 and 1328.1) suggesting good adherence to the protocol. It is worth noting that, participants were unable to wear the activity monitor for the full 1440 minutes on the first and last days of their programme because they started wearing monitors part-way through the day (Session 1 was scheduled between 08:30 and 20:00) and removed them before midnight on their final day.

6.3 Physical Activity Behaviour Change

In order to comprehensively evaluate Physical Activity in the context of health, KiActiv® measures Physical Activity in multiple dimensions, each of which is independently important. Behaviour change was assessed from a blind baseline during the first week of the programme.

97.1% of patients improved Physical Activity

The KiActiv® Health programme significantly improved physical activity in all five dimensions of physical activity (Table 4).

	BASELINE	OPTIMAL	Mean change	P Value*
	Mean (SD)	Mean (SD)	from baseline (95% CI)	(one-tailed)
<i>Physical activity dimension</i>				
Sedentary time (mins/day)	724.74 (102.50)	638.8 (124.91)	-85.94 (-70.99, -100.89)	<0.00001
Moderate activity (mins/day)	69.31 (60.52)	111.37 (76.67)	42.06 (34.87, 49.26)	<0.0001
Moderate bouts (mins/wk)	117.16 (223.30)	253.08 (287.55)	135.92 (111.35, 160.49)	<0.00001
Vigorous bouts (mins/wk)	2.77 (19.43)	9.09 (33.56)	6.32 (2.25, 10.39)	0.0002
Calorie Burn (kcal/day)	2977.37 (609.63)	2346.96 (688.11)	269.60 (222.86, 316.33)	<0.0001

The percentage of patients who improved their physical activity in each dimension were:

Daily Sedentary Time	Daily Moderate Activity	Weekly Moderate Bouts	Weekly Vigorous Activity	Daily Calorie Burn
95.6%	95.6%	86.9%	11.7%	94.9%

83.9% improved in 4 or more Physical Activity dimensions

The proportion of patients who improved in each physical dimension is reflective of the proportion who reported making the conscious decision to improve in that dimension, with the highest proportion (84.5%) choosing to improve their Daily Moderate Activity and the lowest proportion (10.3%) choosing Vigorous Bouts. This gives important insight into why structured exercise programmes have been ineffective – the focus on sport and fitness activities (predominantly of vigorous-intensity) does not align with the interests of the individuals referred to these programmes.

Individuals with diabetes are among the least likely to engage in regular physical activity³¹, undertaking less physical activity than non-diabetic individuals^{32,33}. Up to one third of adults with diabetes are completely sedentary, with only a third taking some form of physical activity regularly^{34,35}. This level of inactivity has not improved since. Indeed, studies have demonstrated that in the absence of a physical activity intervention, individuals with diabetes may not change³⁶, or even decrease³⁷ their physical activity levels.

Patients who successfully changed their activity during the KiActiv® Health programme achieved average improvements of:

Daily Sedentary Time	Daily Moderate Activity	Weekly Moderate Bouts	Weekly Vigorous Bouts	Daily Calorie Burn
1hr 29mins	44 mins	2hrs 36mins	54 mins	284 kcal
12.4%	64.8%	230.6%	1969.5%	equivalent to 13.5kg per year weight loss*

On enrolment to the KiActiv® Health programme patients felt completely reliant on health professionals for the management of their condition and now have an overwhelming appetite to get an element of control over their health again. They want to feel empowered and less vulnerable. Patients have a desire to gain knowledge and understanding of how Physical Activity can benefit them and how it will help their diabetes and other co-morbidities.

In contrast to the traditional conceptually-narrow approaches to Physical Activity, the multidimensional Physical Activity profiles visualised in KiActiv® Health provided the patients with sufficient information about the important aspects of their behaviour. Further, they enabled individuals to develop tailored Physical Activity solutions that align with their interests, needs and circumstances, and are sustainable.

91.4%

of patients felt confident that they could manage their physical activity for their *DIABETES* now and in the future

89.7%

of patients felt confident that they could manage their physical activity for their *OVERALL HEALTH* now and in the future

In order to successfully change Physical Activity behaviours, it was vitally important that patients could understand the visualisations in the KiActiv® web platform and that this enhanced knowledge of personal Everyday Physical Activity. The personal impact of this is reflected in patient quotes and testimonials, demonstrating that they valued the technology-enabled feedback and innovative multidimensional portrayal of Physical Activity displayed in KiActiv® Health web platform, acknowledging an enhanced understanding of their own Physical Activity in response to receiving personalised feedback in the KiActiv® Health platform.

96.5% of patients improved their understanding of Physical Activity

Before starting the KiActiv® Health programme, the majority of patients thought of Physical Activity in terms of leisure-time activities, like sports and fitness classes. Patients found aspects of their own feedback surprising and revealing, demonstrating a misalignment between their perceptions and the reality of their lifestyle.

“Better awareness of the benefit of activities previously thought of as insignificant. Be more active and endeavour to increase my activity level in all my daily activities.”

Male, 61yrs, T1DM

“It showed me that all movement counts not just exercising at the gym...It showed lots of my activities which I had never really considered as exercise!”

Female, 64yrs, T2DM

“The explanation that a little more adds a lot to the end has changed my attitude completely about my health. I always thought there had to be great effort in becoming fitter, but now knowing it is in real terms just a bit of thought that can improve much of one's fitness.”

Male, 64yrs, T2DM

In line with the scientific evidence, the improved understanding of their current Physical Activity helped patients identify their relative strengths and short comings, make more informed decisions on how to improve their Physical Activity and to set realistic goals³⁸. Further, the detailed minute-

by-minute Physical Activity patterns helped them to identify their active and inactive time, which effectively communicated how even small changes can be important for health benefits³⁹.

"It has given me something to focus on and can see how small adjustments can have a big impact on lifestyle and managing your expectations."

Female, 65yrs, T1DM & Arthritis

"Seeing my daily activity graph has really brought home to me how static I was and the benefits of doing exercise."

Male, 80yrs, T1DM

"The main benefit was being able to accurately ascertain the periods of daily activities. In identifying them it was possible to take measures to improve their levels."

Male, 72yrs, T2DM

The emphasis on Everyday Physical Activity proved accessible and engaging, allowing patients to change in a way that was most appropriate to them. Patients now recognise that most forms of Physical Activity have beneficial effects, reporting that activities such as daily chores and active commuting offered them realistic and sustainable ways to include more Physical Activity into their lifestyles.

"Who would have thought doing the washing was an activity, a moderate activity. If I've got 2 things to carry, then I go twice instead of carrying them together"

Female, 86yrs, T2DM

"The whole project has been an eye-opener. Yes, you can buy something that measures your steps, but that's not the whole story. Little and often is almost better than something major and then nothing at all."

Male, 66yrs, T2DM

"It shows up what you do and what you don't do. I wouldn't have called cleaning and cooking activity"

Male, 82yrs, T2DM

Shifting the narrative away from sport and fitness, enabled patients to develop a sense of the attainable and volitional solutions shown to improve the quality of their motivation and prolonged engagement in Physical Activity⁴⁰. When people feel and see the difference they have made for themselves, they are most engaged and motivated. Importantly, empowerment comes from the feeling that they are in control, doing something to help themselves and knowing that what they are doing is right for them.

"I learnt so much in a relatively fast time about myself and the bad things that I didn't know I was doing. It is in short, very easy to become much fitter and aware of one's own body without working oneself to death. The reason it is not hard work is because most of what you do is natural, so natural in fact that now I have finished the programme I continue to keep up with all I have learnt without looking at it as working."

Male, 64yrs, T2DM

"Started to become more aware of my whole life structure and moving in small steady steps which over a period of weeks showed great progress which encourages you to look for more ways to improve your life."

Female, 65yrs, T1DM & Arthritis

Further, the benefits were not isolated to the individual taking part, friends and family members also benefitted from patients' participation in the KiActiv® Health programme.

"By my results of my downloads my husband could see the sense in exercising more so therefore has also started walking more after meals. Also deciding to walk instead of taking the car on short journeys."

Female, 67yrs, T2DM & Cancer

"I've been walking with my husband. He has also seen an improvement in his wellbeing."

Female, 43yrs, T2DM

"It has got my wife walking as well, and we are now looking into getting our bicycles out after 2 years in store!"

Male, 80yrs, T1DM

6.3.1 Clinical outcomes

6.3.1.1 Diabetes Specific Outcomes

Using published research from Umpierre and colleagues¹⁶ we can demonstrate HbA_{1c} improvements that are comparable with diet and drug interventions. As a result of the Physical Activity change, 60% of the group achieved Physical Activity levels shown to reduce HbA_{1c} by 0.9%.

However, it is worth noting that current Physical Activity studies are limited by focusing on one type of activity (and often only changing by a small amount), where compliance is not objectively measured. For example, Sedentary Behaviour is known to have a distinct impact on blood glucose, over and above moderate activity⁴¹, and, as such, this indicates that the effect of our Physical Activity improvements on glycaemic control is likely to be better than reported. This is highlighted by patient data from Primary Care, which showed that much higher reductions in HbA_{1c} were seen in individuals who improved Physical Activity (e.g. 84mmol/l in December 2016 and 43mmol/l in June 2017 or 3.7%).

"It has given me a better awareness of the need to exercise in every possible way throughout the day to increase body activity with the result that my overnight blood glucose sugar level in the morning on waking is averaging 7.5 whereas previously it was getting up to 13.00.

My understanding of diabetes, the importance of body activity and eating sensibly has helped me to now keep recording consistently low blood glucose levels which I had not been able to achieve previously."

Male, 70yrs, T2DM

Qualitative evaluation undertaken during the KiActiv® Health programme demonstrated a reduction in medication as a result of improved glucose management through Physical Activity. This presents the opportunity to reduce the overall costs associated with Diabetes management through a reduction in medications. The National Institute of Health and Care Excellence (NICE) guidance on the management of type 2 diabetes in adults⁴ recommends that if HbA_{1c} levels are not adequately controlled by a single drug, further dietary, lifestyle and adherence advice be

reinforced. This recommendation is prior to intensifying drug treatment, and therefore KiActiv® Health could result in immediate savings through the prevention of second-line drug treatment. Second-line treatment options are often costly, and of course carry side-effects that may adversely impact the patient. According to Prescription Cost Analysis, England – 2016⁴², 72% of the costs of “Antidiabetic drugs” (BNF 6.1.2) are attributable to “Other Antidiabetic Drugs” (BNF 6.1.2.3), which excludes Metformin and Sulfonylureas. Using this ratio, we can estimate the proportion of Antidiabetic Drug spend that relates to second and third line drug interventions in Gloucestershire. According to data from OpenPrescribing.net the total spending on additional drug treatments in 2016 would then equate to £3.04 million⁴³. Therefore KiActiv® Health has the potential to result in significant and immediate (in-year) savings as a result of preventing or replacing second-line drug interventions to manage HbA_{1c}. Further to reducing the cost of medications for Diabetes, Physical Activity will also impact cardiovascular risk, blood pressure, depression and anxiety, and pain/mobility, all of which have associated medicine costs.

Robust evidence demonstrates that improving HbA_{1c} is also associated with a reduction in risk of diabetic complications and therefore relates to further potential healthcare cost savings as a result of changes to Physical Activity over time. Evidence from Stratton and colleagues⁴⁴ indicates that our 0.9% reduction in HbA_{1c} is associated with a risk reduction of 32.9% for microvascular endpoints. The research found a median follow up time of 10.4 years. Whilst we can argue that there will be some benefit prior to this, for the purposes of modelling economic benefit we will use the 10-year timeframe.

Hex and colleagues⁴⁵ suggest that 80% of the £9.8bn spent by the NHS on Diabetes is due to complications and Caro and colleagues⁴⁶ suggest that 48% of this cost burden is due to microvascular complications. The diabetes population of Gloucestershire represents just over 1% of the national diabetes population⁴⁷, therefore we can assume that spending will be closely proportionate to this. We can therefore estimate a potential 10-year saving of £13.5 million for Gloucestershire and adjust appropriately for cohort size.

6.3.1.2 Impact on co-morbidities

Physical inactivity is the fourth leading risk factor for global mortality⁴⁸ and is linked to the development of numerous chronic diseases like Heart Disease, Stroke, Dementia, Obesity, Depression, and certain Cancers^{5,6,7}. Therefore, the sustainable Physical Activity improvements evidenced by KiActiv® Health can be used to model the reduction in co-morbidities and estimate the potential health benefit and cost savings.

Patients identified positive impacts on other conditions and aspects of the mental and physical wellbeing, such as a patient who also had Chronic Obstructive Pulmonary Disease (COPD) who stopped using her stair lift and mobility scooter due to the positive changes made. This demonstrates the broad benefits of Physical Activity, which can act as a foundation for greater personal responsibility for health.

“I've walked everywhere, I go up and down stairs quite a lot. I've been out gardening and doing things I wouldn't normally be doing. I haven't used my mobility scooter or stair lift this year.”

Female, 68yrs, T2DM & COPD

“I've only used my mobility scooter once in the past month. I'd usually use it every time I go out.”

Male, 65yrs, T2DM & Chronic Back Pain

We have used the Sport England MOVES tool (Version 2, November 2016), utilising our objectively measured behaviour change to populate the model. It is worth noting that this model is limited by the fact that it focuses on a single dimension of Physical Activity and restricts the maximum to 70 MET.hrs/week.

6.3.1.3 Health and Wellbeing

Qualitative evaluation identified a number of positive ‘side-effects’ relating to Physical Activity improvements. These ‘side-effects’, which occurred within the 12-week programme related to a number of mental and physical wellbeing outcomes. As a result of the KiActiv® Health programme and the improvements in Physical Activity the following benefits were reported:

- Weight Loss
- Dietary Changes
- Reduction in Chronic Pain
- Improved Mobility
- Reduction in Fatigue
- Improved Mood

Whilst we are unable to currently model the economic benefit for improved wellbeing, due to a lack of clinical data (e.g. reductions in pain medications and falls were not recorded), we can demonstrate the short-term benefits of improved health and wellbeing through productivity gains. The NICE Physical Activity Return on Investment Tool provides guidance on estimating productivity gains through its Technical Report. This information has been used to calculate the potential economic benefit.

In the current project, weight management goals varied; patients reported having weight loss, maintenance and gain goals. However, most patients did not report a weight-related goal. Forty-three patients reported having lost weight, with an average weight loss of 2.7kg (2.96%).

“I can say with some conviction the programme is brilliant it enabled me with the graphs, and visual aids to determine a safe way to monitor my health, see at a glance my exercise levels, and how many calories I was using. I personally used this information to gently step up my exercise levels, and slightly change my diet to safely lose weight (I lost about a stone). Being a type 2 diabetic, this could only be good.”

Male, 64yrs, T2DM

6.3.2 Economic Analysis

Economic benefit is achieved through the improvement in health outcomes, the reduction in future costs such as medicines, complications and co-morbidities, and productivity gains. The programme also demonstrated the opportunity to evaluate the wider impact on prescribing and healthcare usage for other conditions.

We have modelled the economic benefit of the improvements in Physical Activity seen as a result of KiActiv® Health. These benefits occur from Medicine reductions, the reduction of Microvascular Complications, Healthcare Cost Savings and QALY benefit from reducing the risk of future co-morbidities, and productivity gains (note: there are many proven benefits to Physical Activity

which have not been included in this model). From this economic analysis we are able to estimate the Net Economic Benefit at Year 1, Year 5 and Year 10. These figures represent the Total Economic Benefit, adjusted for the Intervention Costs, and discounted according to HM Treasury guidance.

For this model we have assumed a cohort of 500 patients. One hundred patients have been allocated from the Diabetes Digital Coach NHS Test Bed, and as such this lowers the commissioning amount to 500 patients. The average cost per patient equates to £139.99, and therefore the Intervention Cost in this example is £69,995.

Table 5. Net Economic Benefit at Year 1, Year 5 and Year 10 (N=500)

<i>Benefits</i>	<i>Year 1</i>	<i>Year 5</i>	<i>Year 10</i>
Medicine Reduction	£51,074.48	£238,675.07	£439,633.08
Microvascular Complications Reduction	£-	£-	£204,068.07
Healthcare Savings from Fewer Co-morbidities	£18,865.00	£157,178.00	£463,696.00
QALY Benefits from Fewer Co-morbidities	£12,000.00	£254,000.00	£1,112,000.00
Productivity Gains from Improved Wellbeing	£95,065.47	£444,248.47	£818,293.77
Total Economic Benefit	£177,004.95	£1,094,101.55	£3,037,690.91
Net Economic Benefit	£107,009.95	£1,024,106.55	£2,967,695.91
ROI for every £1 spent	£2.53	£15.63	£43.40

Additionally, to help demonstrate the spread of economic benefit across the timeframe and beyond we can plot the ROI graphically.

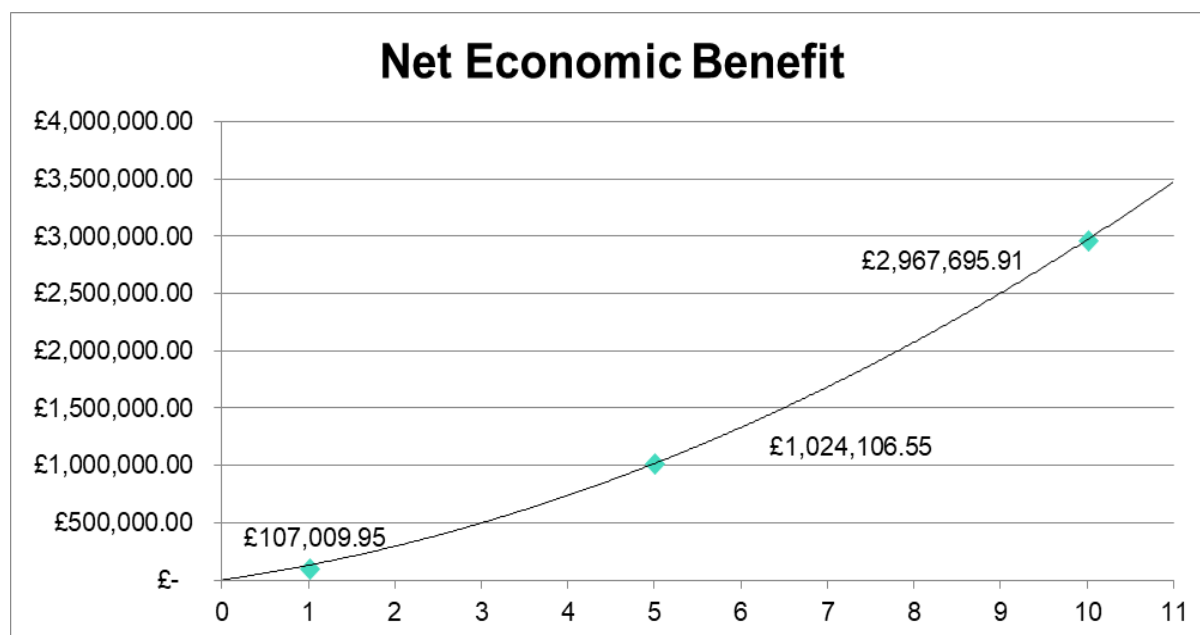


Figure 8. Net Economic Benefit at Year 1, Year 5 and Year 10 (N=500)

As we can see from Table 5 and the Figure 8, the programme delivers a positive ROI by the end of Year 1. This business case provides the economic argument for commissioning the service more widely.

7 Concluding remarks

Patients showed a remarkable appetite to improve their self-management of Diabetes using their Everyday Physical Activity and gain an element of control to reduce their reliance on healthcare professionals.

Despite the age demographics and high incidence of co-morbidities, the emphasis on Everyday Physical Activity proved accessible and engaging, allowing participants to change in a way that was most appropriate to them, achieving health benefits despite their own personal challenges. Further analysis of the patient demographics demonstrates that KiActiv® Health was also accessible and engaging to both men and women of all ages across the deprivation scale. These findings demonstrate the programmes' positive impact on inequalities and highlight the opportunity to spread the use of Physical Activity as a medicine more broadly within primary care. Furthermore, the use of Everyday Physical Activity was significantly more effective at engaging men compared to traditional exercise on referral and group based, diet focussed weight management interventions.

KiActiv® Health was proven to be effective at increasing Physical Activity in people with Diabetes, and these changes were shown to be statistically significant in each of the independently important dimensions. Improvements in Physical Activity are known to have a beneficial impact on the management of Diabetes, and further to this, the levels of behaviour change demonstrated are associated with similar HbA_{1c} reductions to commonly prescribed drug interventions.

In addition to the positive impact on diabetes self-management, the improvements in Everyday Physical Activity were also shown to be beneficial to the management of co-morbidities, such as COPD, reduce future disease risk and improve mental and physical wellbeing. This highlights the opportunity to further strengthen the analysis of potential cost savings by also looking at medicine reductions for other conditions, pain and mental health.

The results also present the opportunity to use Everyday Physical Activity as a Medicine to support the transition from condition specific pathways to a more holistic patient centric service. Measurable health benefit can be demonstrated across multiple mental and physical health pathways, and as such provides a cost-effective intervention to improve self-care and personal responsibility in line with the Five Year Forward View.

A spend-to-save business case, driven by the remarkable improvements in Physical Activity and associated health benefits has been successfully submitted to NHS Gloucestershire CCG, and as a result KiActiv® Health will be offered to a further 500 people with Diabetes across Gloucestershire. Recruitment will focus on people with Type 2 Diabetes, identified from the GP Practices with higher levels of deprivation.

Furthermore, having demonstrated success in improving Everyday Physical Activity in an ageing population for health benefit, other conditions and pathways within NHS Gloucestershire CCG have been identified where this programme could have a positive impact. As such, a business case has been prepared for its use as an accessible digital option for those declining face-to-face strength and balance classes in a falls prevention pathway.

8 Appendix

8.1 Appendix 1 – Invitation Letter

Letter Format:

[date]

Dear [name]

Physical Activity is a powerful Medicine for managing your diabetes but it is not just about exercise and sport – every move you make can count!

The doctors at [Surgery Name] would like to show you how to benefit from your everyday activities and make the right choices for your health.

You will be using unique new technology that includes a clinically proven online platform, an accurate movement tracker and the support of a KiActiv® Mentor. With this new understanding you can improve your diabetes and your motivation to make sustainable changes. This is your chance to take control and become your own health expert – the benefits will last forever.

This opportunity is being offered to you as part of a local partnership between [Surgery Name], the West of England Academic Health Science Network and NHS Gloucestershire Clinical Commissioning Group. The project is looking to understand how technology can support people to better self-manage their Diabetes and is part of the Diabetes Digital Coach, which is supported by Diabetes UK.

Please join us for this trial of a clinically proven personalised 12-week programme, which will empower you to make the right choices for your health.

The programme is currently limited to 100 people over the next 6 months and the first 50 places will be allocated on [date]. Please respond no later than [date]; places will be allocated on a first come first served basis.

To find out more about the programme or to take up this opportunity, please visit diabetes.kiactiv.com or telephone KiActiv® on 01932 851440 (please **DO NOT** contact [Surgery Name]).

Yours sincerely

Text Format:

The Doctors at [Surgery Name] would like to help you improve your diabetes by making the most of your Everyday Physical Activity using the latest technology. To find out more please visit diabetes.kiactiv.com or call KiActiv® on 01932 851440.

9 References

1. Prescription4Exercise (2014). Type 2 Diabetes & Physical Activity. http://prescription4exercise.com/wp-content/uploads/2014/02/P4E-Type-2-Diabetes_NEW_FORMAT.pdf
2. Church T.S. *et al.* (2005). Cardiorespiratory fitness and body mass index as predictors of cardiovascular disease mortality among men with diabetes. *Archives of Internal Medicine*, **165**, 2114-2120.
3. National Institute for Health and Care Excellence (2015). Type 1 diabetes in adults: diagnosis and management, NG17. London, England: National Institute for Health and Care Excellence.
4. National Institute for Health and Care Excellence (2015). Type 2 diabetes in adults: management, NG28. London, England: National Institute for Health and Care Excellence.
5. Physical Activity Advisory Committee (2008). *Physical Activity Guidelines Advisory Committee Report*, Part G. 2008.
6. Brooks, G.A., Butte, N.F., Rand, W.M., Flatt, J.P., and Caballero, B. (2004). Chronicle of the Institute of Medicine physical activity recommendations: how a physical activity recommendation came to be among dietary recommendations. *American Journal of Clinical Nutrition*, **79**, 921-930.
7. Department of Health (2004) *At least five a week; Evidence on the impact of physical activity and its relationship to health*. London: DoH.
8. NHS England, Care Quality Commission, Health Education England, Monitor, Public Health England, Trust Development Authority (2014). *NHS five year forward view*. London, England: NHS England. Available at: <https://www.england.nhs.uk/five-year-forward-view/>, accessed: 30.05.2018.
9. Nathan, D.M., Buse, J.B., Davidson, M.B., Ferrannini, E., Holman, R.R., Sherwin, R., Zinman, B. (2009). Medical management of hypoglycaemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy. *Diabetes Care*, **32(1)**, 193-203.
10. Duclos, M., Dejager, S., Postel-Vinay, N., di Nicola, S., Quére, S., and Fiquet, B. (2015). Physical activity in patients with type 2 diabetes and hypertension – insights into motivations and barriers from the MOBILE study. *Vascular Health and Risk Management*, **11**, 361-371.
11. Andrews, R.C., Cooper, A.R., Montgomery, A.A., Norcross, A.J., Peters, T.J., Sharp, D.J., Jackson, N., Fitzsimons, K., Bright, J., Coulman, K., England, C.Y., Gorton, J., McLenaghan, A., Paxton, E., Polet, A., Thompson, C., and Dayan, C.M. (2011). Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: the Early ACTID randomised controlled trial. *Lancet*, **378**, 129-139.
12. Sport and Recreation Alliance (2012). *Game of life: How sport and recreation can make us happier, healthier and richer*. London, England: Sport and Recreation Alliance. Available at: http://www.sportandrecreation.org.uk/sites/sportandrecreation.org.uk/files/web/Game_of_Life/3310_SRA_literary%20%review_v9%20WITH%20HYPERLINK.pdf
13. Kujala, U.M. (2009). Evidence on the effects of exercise therapy in the treatment of chronic disease. *British Journal of Sports Medicine*, **43**, 550-555.
14. Smutok, M.A., Reece, C., Kokkinos, P.F., Farmer, C., Dawson, P., Shulman, R., DeVane-Bell, J., Patterson, J., Charabogios, C., Goldberg, A.P., and Hurley, B.F. (1993) Aerobic versus strength training for risk factor intervention in middle-aged men at high risk for coronary heart disease. *Metabolism*, **42**, 177-184.
15. Miller, J.P., Pratley, R.E., Goldberg, A.P., Rubin, M., Treuth, M.S., Ryan, A.S., and Hurley, B.F. (1994). Strength training increases insulin action in healthy 50- to 65-yr-old men. *Journal of Applied Physiology*, **77**, 1122-1127.
16. Umpierre, D., Ribeiro, P.A.B., Kramer, C.K., Leitão, C.B., Zucatti, A.T.N., Azevedo., Gross, J.L., Ribeiro, J.P., and Schann, B.D. (2011). Physical activity advice only or structured exercise training and association with HbA_{1c} levels in type 2 diabetes. *JAMA*, **305(17)**, 1790-1799.

17. Snowling, N.J. and Hopkins, W.G., (2006). Effects of different modes of exercise training on glucose control and risk factors for complications in type 2 diabetic patients: a meta-analysis. *Diabetes Care*, **29**, 2518-2527.
18. Thomas, D.E., Elliot, E.J. and Naughton, G.A. (2006). Exercise for type 2 diabetes mellitus. *Cochrane Database Systematic Reviews*, **3**, CD002968.
19. Boule, N.G., Haddad, E., Kenny, G.P., Wells, G.A., and Sigal, R.J. (2001). Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. *Journal of the American Medical Association*, **286**, 1218-1227.
20. Diabetes UK, (2017). *Diabetes education and self-management*. London, England: Diabetes UK. Available at: <https://www.diabetes.org.uk/professionals/resources/shared-practice/diabetes-education>, accessed: 30.05.2018
21. Ryan, R.M., Patrick, H., Deci, E.L., and Williams, G.C. (2008). Facilitating health behaviour change and its maintenance: interventions based on self-determination theory. *European Health Psychologist*, **10(1)**, 2-5.
22. Stead, M., Gordon, R., Angus, K., and McDermott, L. (2007). A systematic review of social marketing effectiveness. *Health Education*, **107(2)**, 126-191.
23. Stead, M., Hastings, G. and McDermott, L. (2007). The meaning, effectiveness and future of social marketing. *Obesity Reviews*, **8**, 189-193.
24. Western, M.J., Peacock, O.J., Stathi, A., and Thompson, D. (2015). The understanding and interpretation of innovative technology-enabled multidimensional physical activity feedback in patients at risk of future chronic disease. *PLoS ONE*, **10(5)**, e0126156. doi:10.1371/journal.pone.0126156.
25. Fortier, M.S., Williams, G.C., Sweet, S.N., and Patrick, H. (2009). Self-determination theory: Process models for health behaviour change. In: *Emerging theories in health promotion practice and research: Strategies for improving public health, 2nd edition*. Edited by DiClemente, R.J., Crosby, R.A., and Kegler, M.C. San Fransisco, CA: John Wiley & Sons, pp.157-183.
26. Williams, G.C. (2002). Improving patients' health through supporting the autonomy of patients and providers. In: *Handbook of Self-Determination Research*. Edited by Deci, E. and Ryan, R. Rochester, NY: Rochester Press, pp. 233-254.
27. Wilson, P.M., Mack, D.E. and Grattan, K.P. (2008). Understanding motivation for exercise: A self-determination theory perspective. *Canadian Psychology/Psychologie Canadienne*, **49(3)**, 250-256.
28. Fortier, M. and Kowal, J. (2007) the flow state and physical activity behaviour change as motivational outcomes: A self-determination theory perspective. In: *Self-determination Theory in Exercise and Sport*. Edited by Hagger, M. and Chatzisarantis, N. Champaign, Il: Human Kinetics, pp.113-125.
29. Biddle, S.J.H and Nigg, C.R. (2000) Theories of exercise behaviour. *International Journal of Sport Psychology*, **31**, 290-304.
30. Peacock, O.J., Western, M.J., Batterham, A.M., Stanthi, A., Standage, M., Tapp, A., Bennett, P., and Thompson, D. (2015). Multidimensional individualised Physical ACTivity (Mi-PACT) – a technology-enabled intervention to promote physical activity in primary care: study protocol for a randomised controlled trial. *Trials*, **16(1)**, 381.
31. Qiu, S., Sun, Z., Cai, X., Liu, L., and Yang, B. (2012). Improving patients' adherence to physical activity in diabetes mellitus: a review. *Diabetes and Metabolism Journal*, **36**, 1-5.
32. Egede, L.E. and Zheng, D. (2002). Modifiable cardiovascular risk factors in adults with diabetes. Findings from the 1990 National Health Interview Survey – Health Prevention and Disease Prevention Supplement. *Diabetes Care*, **162**, 427-433.
33. Ford, E.S. and Herman, W.H. (1995). Leisure-time physical activity patterns in the US diabetic population. Findings from the 1990 National Health Interview Survey – Health Prevention and Disease Prevention Supplement. *Diabetes Care*, **18**, 27-33.
34. Thomas, N., Alder, E., and Leese, G.P. (2004). Barriers to physical activity in patients with diabetes. *Postgraduate Medical Journal*, **80**, 287-291.

35. Nelson, K.M., Reiber, G. and Boyko, E.J. (2002). Diet and exercise among adults with type-2 diabetes (findings from NHANES III). *Diabetes Care*, **25**, 1722-1728.
36. Kooiman, T.J.M., de Groot, M., Hoogenberg, K., Krijnen, W.P., van der Schans, C.P., and Kooy, A. (2018). Self-tracking of physical activity in people with type 2 diabetes: a randomised controlled trial. *CIN: Computers, Informatics, Nursing*, **36(7)**, 340-349.
37. Kirk, A., Mutrie, N., MacIntyre, P., and Fisher, M. (2003). Increasing physical activity in people with type 2 diabetes. *Diabetes Care*, **26**, 1186-1192.
38. DiClemente, C.C., Marinelli, A.S., Singh, M., and Bellino, L.E. (2001). The role of feedback in the process of health behaviour change. *American Journal of Health Behaviour*, **25**, 217-227.
39. Erikssen, G. (2001). Physical fitness and changes in mortality: the survival of the fittest. *Sports Medicine*, **31**, 571-576.
40. Standage, M. and Ryan, R.M. (2012). Self-determination theory and exercise motivation: Facilitating self-regulatory processes to support and maintain health and well-being. In: Robert, G.C., Treasure, D.C. editors. *Advances in motivation in sport and exercise*. 3rd ed. Champaign, IL: Human Kinetics, pp 233-270.
41. Hamilton, M.T., Hamilton, D.G., and Zderic, T.W. (2014). Sedentary behaviour as a mediator of type 2 diabetes. *Medicine and Sport Science*, **60**, 11-26.
42. NHS Digital, (2017). *Prescription Cost Analysis – England, 2016*. London, England: NHS Digital. Available at: <https://digital.nhs.uk/data-and-information/publications/statistical/prescription-cost-analysis/prescription-cost-analysis-england-2016>, accessed on: 18.12.2017
43. OpenPrescribing, EBM DataLab, University of Oxford (2017). *Search GP prescribing data*. Available at: <https://openprescribing.net/analyse/#org=CCG&orgIds=11M&numIds=6.1&denom=nothing&selectedTab=summary>, accessed on: 18.12.2017
44. Stratton, I.M., Adler, A.I., Neil, A.W., Matthews, D.R., Manley, S.E., Cull, C.A., Hadden, D., Turner, R.C., and Holman, R.R. (2000). Association of glycaemia with microvascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *British Medical Journal*, **321**, 405-412.
45. Hex, N., Bartlett, C., Wright, D., Taylor, M., and Varley, D. (2012). Estimating the current and future costs of type 1 and type 2 diabetes in the UK, including direct health costs and indirect societal and productivity costs. *Diabetic Medicine*, **29**, 855-862.
46. Caro, J.J., Ward, A.J. and O'Brien, J.A. (2002). Lifetime costs of complications resulting from type 2 diabetes in the US. *Diabetes Care*, **25(3)**, 476-481.
47. NHS Digital, (2016). *Prescription Cost Analysis – England, 2016*. London, England: NHS Digital. Available at: <https://digital.nhs.uk/data-and-information/publications/statistical/quality-and-outcomes-framework-achievement-prevalence-and-exceptions-data/quality-and-outcomes-framework-qof-2015-16>, accessed on: 18.12.2017
48. Murray, C.J.L., Richards, M.A., Newton, J.N., Fenton, K.A., Anderson, H.R., Atkinson, C., Bennett, D., Bernabé, E., Blencowe, H., Bourne, R., Braithwaite, T., Brayne, C., Bruce, N.G., Brugha, T.S., Burney, P., Dherani, M., Dolk, H., Edmond, K., Ezzati, M., Flaxman, A.D., Fleming, T.D., Freedman, G., Gunnell, D., Hay, R.J., Hutchings, S.J., Lockett Ohno, S., Lozano, R., Lyons, R.A., Marcenes, W., Naghavi, M., Newton, .R., Pearce, N., Pope, D., Rushton, L., Salomon, J.A., Shibuya, K., Vos, T., Wang, H., Williams, H.C., Woolf, A.D., Lopez, A.D., and Davis, A. (2013). UK health performance: findings of the Global Burden of Disease Study 2010. *The Lancet*, **381**, 997-1020.