The Future Challenges

Keeping Healthy at Home:

Replenish-ME











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The Future Challenges: Replenish-ME

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¹ KiActiv[®] is the trading name of Ki Performance Lifestyle Limited

This real-world validation project was delivered as a collaboration between all project partners. The project report has been co-written, with the data analysis and evaluation being conducted by the South West AHSN.

The project was undertaken during the Covid-19 pandemic, the delivery of the intervention and timescales were adjusted as necessary, to accommodate government guidance and lock downs.

Assurance rating

* This report can be used for context and background information	
** This report can help inform decision making, when considered with other information	X
*** This report is the best available evidence to date	

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Executive summary

Background

The <u>Future Challenges programme</u> is a central part of the <u>West of England Academic</u> <u>Health Science Network (AHSN)'s</u> remit to assist industry, and work with the NHS to adopt and spread innovative products and services, to benefit patients and to encourage economic growth in the UK. The programme identifies and articulates local healthcare challenges and connects healthcare professionals with small to medium enterprises (SMEs) to support the development of healthcare solutions. Following engagement with local experts across the <u>West of England</u>, a national call for innovative solutions under the theme of "Keeping Healthy at Home" was launched and focused on two main areas: staying well and confident, and staying connected and supported.

<u>KiActiv</u>[®]'s technology, KiActiv[®] Health was selected, along with the <u>Bath Centre for Fatigue</u> <u>Services (BCFS)</u> at the Royal National Hospital for Rheumatic Diseases (RNHRD), part of the Royal United Hospitals Bath NHS Foundation Trust, who were keen to trial the technology. Specialist evaluators, based within the <u>South West AHSN</u>, were also selected to assess the impact and effectiveness of this programme.

Innovation

The project evaluated KiActiv[®] Health, a personalised and guided online intervention that empowers participants to optimise physical activity within their everyday lives. KiActiv[®] Health provides an interactive personalised dashboard to display accurate physical activity data and is supported remotely by phone calls with a dedicated mentor over 12-weeks. At the end of the 12-weeks, participants retain access to their personal dashboard and activity monitor, enabling them to continue their self-management using the technology if desired.

Purpose / objective

The "Replenish-ME" project was co-designed to use the KiActiv[®] digital behaviour change programme, in parallel with current services for patients living with Chronic Fatigue Syndrome (CFS) / Myalgic Encephalomyelitis (ME), and explore whether KiActiv[®] Health could help those diagnosed with CFS/ME to develop a greater understanding of how their day-to-day activities impact on their health and energy levels. In the context of CFS/ME, understanding how physical activity impacts on energy balance and how to maintain a level of movement within their energy availability, is an important component of self-management for some.

BCFS is a nationally recognised centre of expertise, providing outpatient-based, specialist assessment and treatments for adults experiencing long standing fatigue. The clinical team were keen to understand how KiActiv[®] Health might work alongside their current programme and evaluate any benefits to the patients and the service.

Methodology

Between February and September 2020, adult patients referred to BCFS with a confirmed diagnosis of CFS/ME were introduced to KiActiv[®] Health by members of the BCFS interprofessional team. Patients enrolled directly with KiActiv[®], who then contacted them to complete the enrolment process, if eligible. 118 patients were informed about KiActiv[®] Health, 43 were recruited and 41 completed the 12-week programme, whilst also engaging in the BCFS programme.

Qualitative and quantitative data was collected. Patients completed a pre- and postintervention questionnaire and data was also collected to demonstrate patients' adherence and engagement. Following completion, patients were asked whether their expectations of the KiActiv[®] Health programme had been met and what had helped or hindered them to use the technology. The evaluation team also reviewed contemporaneous notes taken by the KiActiv[®] Mentors, conducted eight one-to-one semi-structured interviews with the five BCFS clinicians and held one group discussion with four BCFS clinicians. Clinicians were asked about the barriers and enablers to integrating KiActiv[®] Health into the BCFS programme, as well as how implementation of the project had been impacted by COVID-19.

Key findings

36% (n=43) of patients with CFS/ME who were told about the KiActiv[®] Health programme were willing to engage alongside the evidence based BCFS treatment programme, and 95% (n=41) were highly adherent. The impact on patients was reported in some key findings such as: 66% (n=23) of patients reported an improvement in their overall health and 60% (n=16) of patients gained greater awareness of how different activities could impact on their energy expenditure. Analysis of the quantitative data collected at the start and on completion of the programme indicated that patients with CFS/ME experienced a statistically significant improvement in CFAQ-8, EQ5D, awareness and confidence. Providing patients with accurate and comprehensive physical activity data in combination with the specialist clinical treatment given in the BCFS programme, also led to a statistically significant improvement in their awareness of what diminished and restored their energy levels. By helping patients to successfully pace, and with Mentors providing strong encouragement and support, in combination with the BCFS specialist treatments, patients experienced a statistically significant improvement in the confidence they had to manage their daily activities and better use their energy, as well as their ability to pursue life activities regardless of their fatigue. This meant 60% (n=15) of patients were more accepting of their fatigue, culminating in a statistically significant improvement in overall health and the expectations of KiActiv[®] being met or exceeded by 71% of patients (n=29).

Lessons learned and conclusions

High levels of engagement and low dropout rates were seen in the 41 patients that completed the 12-week programme. Although this was a relatively small sample size, it shows some patients with CFS/ME are willing to use KiActiv[®] Health. Statistically significant improvements across a range of outcomes suggests KiActiv[®] Health could be offered as part of a personalised approach to managing CFS/ME for some patients.

Patients' prior values and behaviours are important factors to consider when introducing KiActiv[®] Health; an individual approach to uptake was essential. KiActiv[®] Health was not felt to be appropriate for all patients by the BCFS team, and so having clear eligibility criteria prior to beginning recruitment is key.

Clarity and agreement between all parties about how KiActiv[®] integrates and complements usual care is vital to potential implementation and engagement.

It is acknowledged that there are clear benefits to interventions delivered virtually, particularly during a pandemic. However, clarity regarding the integration of KiActiv[®] Health with personalised care is an important consideration for its application in other settings and patient groups. Future implementation could consider having clinicians who are given devices and trained to facilitate shared learning.

Recommendations

The results from this evaluation indicate that the use of KiActiv[®] can have a positive impact in combination with specialist CFS/ME provision. Key areas for development have been identified to optimise use in this patient cohort and KiActiv[®] has begun scoping some adaptations, which include general user interface (UI) and user experience (UX) upgrades. Further discussion with BCFS clinicians would help to understand the potential opportunity to continue exploring the integration of KiActiv[®] into their service. The West of England AHSN business development team will continue to support KiActiv[®] to further explore a cost-benefit evaluation, development of a business case for CFS/ME and applications of this technology in the landscape of long COVID.



1. Background

The <u>West of England AHSN</u> has a remit to assist industry, particularly small to medium sized enterprises (SMEs), to work with the NHS to adopt and spread innovative products and services to benefit patients and to encourage economic growth in the UK.

The <u>Future Challenges programme</u> is a central part of the West of England AHSN's remit to support innovation in health and care, and is delivered as part of the commission from the Office of Life Sciences to aid the adoption and spread of promising innovations. The aim of the programme is to identify and articulate local healthcare challenges and to develop a system where healthcare professionals can connect with SMEs to stimulate engagement and partnership in supporting the development of healthcare solutions.

This national call for innovative solutions and offer of funding is part of the wider West of England AHSN innovation work, which aims to support the NHS to identify companies to partner with to deliver these solutions. The programme aims to actively nurture an innovation ecosystem around health and care, removing obstacles and bringing diverse groups together to maximise new ways of working.

The West of England AHSN refers to 'challenges' as a means of articulating clinical or healthcare system needs and then describing them in such a way that companies can respond with concepts for development or solutions to meet those needs.

This process frames the areas of need as a 'What If?' question to help innovators think about problems more openly and creatively. An example used for this theme was, 'What if we had technology, knowledge and confidence to manage our own condition?'.

The West of England AHSN engaged with a broad range of local expert networks, to identify areas of need around which we could focus our challenges. The representatives included health service providers and commissioners, voluntary organisations and university researchers from across the <u>West of England AHSN's member organisations</u>. This resulted in the identification of two initial themes:

- Young People and Mental Health Resilience
- Keeping Healthy at Home

The national call for innovative solutions under the theme of Keeping Healthy at Home, focused on two main areas: staying well and confident, and staying connected and supported.

<u>KiActiv</u>^{®'s} technology, KiActiv[®] Health was chosen from a wide range of submissions by an expert panel. A further call then went out across our NHS membership for expressions of interest in hosting a trial and evaluation of the chosen technology. The <u>Bath Centre for</u> <u>Fatigue Services (BCFS)</u> at the Royal National Hospital for Rheumatic Diseases (RNHRD), which is part of the Royal United Hospitals Bath NHS Foundation Trust, was keen to trial

KiActiv[®] Health. In parallel to this, specialist evaluators based within the South West AHSN, were selected through a separate tender to assess the impact and effectiveness of this programme.

The West of England AHSN utilised a co-design-based process with the innovator, NHS organisation host and evaluator. This was used to design and plan a project to explore the potential value of the innovation within the identified patient cohort and evaluate its effectiveness and the potential for ongoing use in a real-world setting.

The resultant project, **Replenish-ME**, was designed to explore whether using the KiActiv[®] Health digital behaviour change service could help patients diagnosed with CFS/ME to develop a greater understanding of how their day-to-day activities impact on their health and levels of energy. And therefore, whether the service could enhance current services for patients living with CFS / ME.

KiActiv[®] Health is a flexible service, designed to empower patient-led behaviour change that is enabled by individual lifestyle insights, and driven by personal goals in the context of their health and condition. KiActiv[®] worked with the clinical team at BCFS to gain valuable feedback on this new patient cohort, and to offer KiActiv[®] Health to patients in order for them to objectively track their physical activity levels, in the context of their health and capabilities.

A key criterion for innovations to be selected for inclusion in the Future Challenges programme was evidence of success elsewhere, perhaps in another clinical area. KiActiv[®] Health is currently in use across a number of locations to support people with Type 2 diabetes, and other long-term conditions. However, this was the first time it has been used within this patient group.

This programme has been a great opportunity for the West of England AHSN to build collaborative relationships between the NHS and SMEs, bringing innovation into practice to potentially solve needs within the health and care community.

2. Clinical context

The Bath Centre for Fatigue Services is a nationally recognised centre of expertise, providing outpatient-based, specialist assessment and treatments for adults experiencing long-standing fatigue, linked to a variety of medical conditions. People referred may be experiencing Post Viral Fatigue Syndrome (PVFS), CFS/ME, Cancer Related Fatigue (CRF) and/or fatigue linked to other long-term conditions, such as joint hypermobility, Parkinson's disease and Multiple Sclerosis.

Since commencing this project, the service has also begun to accept referrals for people experiencing COVID-19 related fatigue. This has been achieved by adapting the 'usual' service offer, to continue to support patients throughout 2020 and into 2021; thereby successfully accommodating the restrictions placed on the NHS by the pandemic. This adaptation is summarised below, along with the usual treatment offer from BCFS.

BCFS's evidence-based provision is based on the ethos of supported self-management, which enables people to better cope with the impact of their health conditions and regain a sense of control over often chaotic day-to-day activities and routines, regardless of their causes.

Provision is tailored within a stratified Comprehensive Personalised Care Model and provided in a variety of geographical locations in the region, and through a variety of media as appropriate. This would usually include face-to-face, Skype and/or Zoom platforms as appropriate.

Fatigue is recognised as being physical, cognitive and/or emotional in nature, and the degree to which individuals are impacted is variable. Supporting people to manage complex biopsychosocial needs and symptoms in the absence of a recognised cure for their condition/s is important. Using expertise from occupational and psychological epistemologies and approaches, the aim of the provision is focused on reducing the impact of fatigue on day-to-day life, facilitating re-engagement with meaningful occupations/activities, improving low mood and reducing levels of health-related anxiety. Data for clinical and research purposes are collected at three points in time: pre-assessment, post treatment and at the six-month follow up.

2.1 BCFS usual service offer

- Tailored/personalised assessment, case formulation and treatment planning agreed jointly with the patient: this is where treatment/intervention commences, and needs are acknowledged and validated.
- Fatigue and lifestyle management includes education and skills development in activity pacing and energy usage, gradual reintroduction of lost occupations due to ill health, including employment, management of stress and anxiety and values-based goal setting, using Adaptation Theory, Cognitive Behavioural and Acceptance and Commitment Therapy principles.

- Validation of experiences of issues relating to living with CFS/ME and facilitation of meaningful and sustainable lifestyle changes for health and well-being.
- Interventions can be delivered either on a one-to-one basis or in a group.

One-to-one: Six individual sessions are offered of up to one hour, over an individually negotiated period of time to suit patient needs/preferences; either in a clinic or virtually. Resources are sent to the individual if seen virtually, otherwise they are issued during face-to face-sessions. A six-month follow-up session is also provided, and, at that point, the patient is usually discharged, or interventions are extended if necessary.

Group programme: Six group sessions of 2.5 hours in a group of eight to 12 people. Spread over six weeks, once a week, during either afternoons or mornings, dependent on patient preference. In a variety of locations on site at the Royal United Hospital or at an outreach location. A six-month follow-up session is also provided, and, at that point, the patient is usually discharged, or interventions are extended if necessary, as per the one-toone sessions.

2.2 Adapted COVID-19 response

The BCFS team relocated to working at home within one week of lockdown in March 2020, and continued to do so until November 2020, when the first Zoom-based groups commenced. At least two to three team members deliver group interventions in a COVID-19 safe environment.

One-to-one: Three individual sessions are offered of up to one hour, over an individually negotiated period of time, to suit patient needs/preferences, virtually via telephone, Skype and/or Zoom. Resources are sent to patients in a paced way as 'homework' in preparation for sessions. A six month follow up session is also provided and at that point the patient is usually discharged, or interventions are extended if necessary.

Group programme: Three virtual group sessions of two hours in a group of maximum five people. These are spread over six weeks and occur once a fortnight, either afternoons or mornings, dependent on patient preference. A six-month follow-up session is also provided, and, at that point, the patient is usually discharged, or interventions are extended if necessary.

One of the resources used to support interventions is the BCFS Activity, Rest and Sleep Log. The aim of using this is to capture perceptions of energy expenditure in terms of physical, cognitive and emotional fatigue/energy. A hard copy of the Log is usually introduced to patients at initial assessment, and they are invited to engage with completion of this, to explore the composition and mix of daily activities, and how these impact on available energy levels; positively and/or negatively. Initially this assists patients to gain some understanding of baseline energy levels and how energy is being used.

Having a raised awareness of this concept can enable the patient to consider whether they are using available energy in a way they find meaningful, and/or whether they could use available energy differently. This process enables potential changes in behaviour, based on their beliefs and values and meaningful occupations and activities. A personal consideration of which activities and occupations use the most energy, and those they consider are restorative, is suggested. The Log is used to capture all activities including showering and bathing and types of energy expenditure i.e., physical, cognitive and emotional as mentioned above. Periods of sleep and wakefulness are also recorded.

2.3 Rationale for evaluating KiActiv[®] Health

It is recognised that the usefulness of the hard copy Log depends on the individual completing this in a timely and meaningful, but subjective, way; resulting in a variation in completeness of the data captured.

The BCFS team was interested to trial the KiActiv[®] Health intervention to explore if it would provide some patients with an alternative, or additional, method of recording engagement in their daily activities/occupations. The intervention was perceived as possibly enabling a more detailed record of individual routines and energy expenditure, than the current Activity Rest and Sleep Logs. For example, using wearable technology, KiActiv[®] Health may record activities that, due to cognitive fatigue, patients forget to record. The real-time recording of activity also offered the potential of providing a more comprehensive and accurate report of physical activity.

Additionally, it was anticipated that the incidences of human error involved in completing the Activity Rest and Sleep Logs, may also be reduced. The team was also interested to explore whether a reduced burden to patients could be achieved through measuring their daily activity via KiActiv[®] Health, as the time and energy dedicated to manual completion would be removed.

The BCFS team was also keen to understand how the KiActiv[®] Health intervention would work alongside its current programme and evaluate any benefits to the patients, service and clinical team.

The evaluation was also seen as offering valuable real-world evidence to support commissioning decisions across the wider health system and to support the ongoing product development and commercialisation of the product for this new patient cohort.

3. The KiActiv® intervention

KiActiv[®] Health is a digital service which provides people with a personalised understanding of their everyday physical activity, and empowers behaviour change in the context of their health and capacity; enabling people to make the right choices for their health.

In the context of CFS/ME, understanding how physical activity impacts on energy balance, and how to maintain a level of movement within their energy availability, is an important component of self-management for some.

Crucial to this understanding is that physical activity is more than just exercise and sport, and that every move you make matters. Physical activity is defined as any bodily movement produced by skeletal muscles that results in energy expenditure, and, as such, it is important that all of the movement in our lifestyles is accounted for, and not just exercise.

KiActiv[®]'s proprietary patented technology evaluates minute-by-minute physical activity data from a validated wearable monitor, cleanses the data, and displays it instantly in the user's personalised online dashboard, which is available 24/7, to provide meaningful and actionable feedback. Telephone support is given by a KiActiv[®] Mentor at key times during the first 12 weeks, helping the user build an understanding of the value of their daily activities and the confidence to plan, monitor and make the most of their available energy, without compulsion or prescription.

The KiActiv[®] Mentors are not clinicians/specialist health professionals, they are specially trained in the use of the KiActiv[®] technology. The reason for this is that the service is based on Self-Determination Theory, and it is important to remove the risk of subjective opinion being given to the user about their personal physical activity, or any other health matter. KiActiv[®] was specifically designed in this way, focusing on authentic self-choice and intrinsic motivation to create sustainable behaviour change, and to enable patient support to be provided at scale.

KiActiv[®]'s unique approach evaluates physical activity across multiple dimensions that are independently important to health. Much like the multiple aspects of diet known to be important, physical activity is a heterogeneous behaviour, which can't be accurately reflected in a single metric. The research from our partners at the University of Bath, published in the Exercise and Sport Sciences Reviews (a journal of the American College of Sports Medicine - click here for article), shows robust evidence that personalised multidimensional physical activity profiles are crucial to providing an accurate and comprehensive understanding of an individual's physical activity. Importantly, this overcomes the danger of developing a false picture of one's physical activities, and its impact on energy balance, which is likely to occur by focusing on one dimension alone, e.g., minutes of moderate intensity physical activity.

Physical activity is defined above in relation to energy expenditure which, in turn, relates to its impact on energy balance. As such, KiActiv[®] measures physical activity by calculating the energy expended through movement for each minute of the day. This enables us to determine the relative intensity of movement in that minute, by using metabolic equivalents (METs), providing accurate and personalised information about the activity being done at that time.

A comment on heart rate as a measure of physical activity

Whilst a number of activity monitors have included a heart rate sensor, heart rate is limited in its accuracy and reliability for estimating individual's energy expenditure. For this reason, KiActiv[®] utilises accelerometer technology to capture energy expenditure at minute-by-minute granularity, creating the opportunity for the provision of personalised multidimensional physical activity profiles and feedback. Further scientific rationale regarding this can be found in Appendix A.



4. Acknowledged limitations of technology and evaluation

The KiActiv[®] technology used in this evaluation was the version used to support patients living with long term conditions, in order to optimise their physical activity levels. The project team recognised that some elements of the platform were not designed specifically for a CFS/ME cohort, and it was acknowledged from the outset that there would be some limitations in its current form. Limitations identified include:

- The KiActiv[®] programme was not specifically designed for people with CFS/ME and the KiActiv[®] Dashboard was not optimised for a chronic fatigue cohort. However, the language used by the Mentors was always in the context of the individual patient's circumstance. A decision was made to ensure users were aware of this and the project team agreed to collect feedback to inform future product enhancements, if appropriate.
- The wearable physical activity monitor is not waterproof, and therefore does not capture water-based energy expenditure, such as showering and swimming. The project team discussed that the planning function of KiActiv[®] online dashboard could allow patients to log an individual, evidence-based estimate of energy expenditure for these types of activities. It is acknowledged that these are activities that may expend relatively high levels of energy for this patient population. It is, however, important to highlight that would be estimated and not actual energy expenditure.
- The KiActiv[®] technology only captures energy expenditure related to physical activity. However, users were able to subjectively record tasks that require high levels of cognitive and emotional energy using the tagging function within the dashboard, as they currently do in the BCFS activity, rest and sleep log. It was acknowledged that these potential product adjustments offer areas for future product development, to fully optimise the use of KiActiv[®] for people with CFS/ME.
- KiActiv[®] Health was delivered as part of a specialist CFS/ME evidence-based service and therefore any positive effects found in this evaluation cannot be attributed solely to the effects of KiActiv[®] Health. Both programmes include active behaviour change techniques that could contribute to the effects found, but the methodology employed within this evaluation is unable to specify which parts of these interventions had the greatest effects. The single group evaluation design means that causality cannot be attributed to either programme in isolation and could be due to natural fluctuations in the outcomes measured. Patients did, however, comment specifically on elements of KiActiv[®] Health and these findings have been highlighted in the results of this evaluation. The small sample size also has implications for the validity and generalisability of these findings to the wider CFS/ME population. The results suggest that patients use KiActiv[®] Health beyond the 12-week programme, but to confirm this, an evaluation with a longer follow-up period would be needed, alongside an assessment of whether this engagement leads to positive effects for patients and the health service.

5. Evaluation

5.1 Evaluation scope

The South West AHSN was commissioned to undertake this real-world evaluation in 2019. The evaluation was co-designed by the West of England AHSN, the South West AHSN, KiActiv[®] and BCFS. A detailed logic model (Appendix B) was developed by the project team to visualise how KiActiv[®] Health produces its intended outcomes. This was then translated into the evaluation questions described below. The aim of the project was to establish the use of real-time objective energy management technology in the BCFS programme, in order to improve patients' abilities to visualise their energy use and to be able to pace their everyday activities. The evaluation aimed to answer the following questions:

- To what extent do patients with CFS/ME who are following the BCFS fatigue programme engage with KiActiv[®] Health?
- What impact does KiActiv[®] Health have on patients when used alongside the BCFS programme?
- Are patients' expectations of KiActiv[®] Health met?
- What are the barriers and enablers to using KiActiv[®] Health from the patient and clinician perspective?
- How has COVID-19 affected the implementation of KiActiv[®] Health?

5.2 Methods

Between February and September 2020, adult patients referred to BCFS with a confirmed diagnosis of CFS/ME were introduced to KiActiv[®] Health by members of the BCFS interprofessional team. Patients were provided with written information and, if interested, asked to enrol directly with the company by phone, email, or online sign-up. The patient was then contacted by KiActiv[®] to ensure that they were eligible to take part in the project and complete the enrolment process. The physical activity monitor was then sent to the patient and a start date arranged. The programme began with a set-up call with a KiActiv[®] Mentor. Data collection combined qualitative and quantitative methods.

5.3 Quantitative data

Objectively measured physical activity

Physical activity, across multiple dimensions, was directly and continuously assessed using data from a validated physical activity monitor throughout the 12-week programme (Figure 1).

- <u>Calorie burn</u>: the total number of calories burned in a 24-hour period from midnight to midnight.
- <u>Non-sedentary time</u>: the amount of time (mins) spent engaging in non-sedentary activity per day. Sedentary behaviour included any waking behaviour characterised by an energy expenditure of <1.8 metabolic equivalents (METs), while in a sitting or lying posture (Swinnen et al., 2014). This included activities such as TV viewing, computer use, reading and driving. It is important to note that some of these sedentary activities may be classed as restorative, whilst other sedentary activities can be cognitively fatiguing for patients with CFS/ME.
- <u>Moderate or higher intensity physical activity</u>: the amount of time (mins) spent engaging in moderate or higher intensity physical activity, defined as anything that made the individual burn more than 3 times the number of calories they burn at rest per day (≥3 METs) (Haskell et al.,

Figure 1: The multiple dimensions of physical activity monitored by KiActiv® Health

Demographic characteristics

At baseline, patients were asked to provide their age, sex, ethnicity, home postcode to calculate deprivation decile (Ministry of Housing, Communities & Local Government 2019), and height and weight to calculate body mass index (BMI).

Self-report questionnaires

Patients were asked to complete a questionnaire at the start and end of the 12-week KiActiv[®] programme, this included:

- The eight-item Chronic Fatigue Acceptance Questionnaire (CFAQ-8), an adapted version of the eight-item Chronic Pain Acceptance Questionnaire (Fish et al., 2010). The CFAQ-8 includes two subscales:
 - o Activity engagement the pursuit of life activities regardless of fatigue
 - Fatigue willingness recognition that avoidance and control are often unworkable methods of adapting to chronic fatigue.
- The Visual Analogue Scale (VAS) from the EuroQol five-dimension (EQ-5D) questionnaire (Rabin et al., 2001) a measure of overall health.
- Two single-item questions, both on a 4-point Likert scale from strongly agree to strongly disagree:

- 1. How aware they were of how everyday activities impacted upon their energy expenditure.
- 2. How confident they were in managing their daily activities in order to best use their energy.

Adherence and engagement

The following data was collected to demonstrate patients' adherence and engagement with KiActiv[®] Health:

- Total number of days that a patient wore the physical activity monitor.
- Total number of complete days that a patient wore the physical activity monitor. A complete day was defined as the monitor being worn for at least 80% of an assumed 16-hour waking day (i.e., wear time ≥768 mins).
- Total number of days on which the patient synced their data using the KiActiv[®] app.
- Total number of days on which the patient visited the KiActiv[®] online dashboard.
- Total number of days on which the patient tagged their activity on the KiActiv[®] online dashboard.

5.4 Qualitative data

Questions derived to collect the following data from patients and BCFS clinicians are shown in Appendix C.

- At the end of the programme patients were asked whether their expectations of KiActiv[®] Health had been met and what had helped or hindered them to use the KiActiv[®] programme.
- The evaluators reviewed the contemporaneous notes taken by the KiActiv[®] Mentors during the five sessions, which included some direct quotes from patients.
- The evaluators conducted eight one-to-one semi-structured interviews with five members of BCFS team and one group discussion with four members of the BCFS team. Clinicians were asked about the barriers and enablers to integrating KiActiv[®] Health into the BCFS programme, as well as how implementation of the project had been impacted by COVID-19.
- The evaluators reviewed the 15 project team meeting minutes.

5.5 Analysis

The analysis techniques used depended on the type of data collected:

- Qualitative data was analysed from the audio recordings using the theoretical domains framework for behaviour change (Cane et al., 2012) or thematic analysis (Braun & Clarke, 2006). This analysis was then used to guide the learning needed for future implementation and spread.
- Wilcoxon's signed rank tests or paired *t* tests were used to analyse changes in the self-report questionnaires and single-item questions over time.

Given that the overall aim of the project was not to increase physical activity, looking at statistically significant changes in physical activity in isolation would have been inappropriate. Quantitative fluctuations in physical activity were therefore interpreted within the context of the contemporaneous notes made by the KiActiv® Mentor. The analysis included plotting physical activity for each participant and triangulating this data with the date of the KiActiv[®] Mentor session and the themes emerging in the notes. It is important to remember that these notes were the Mentor's interpretation of the discussion, with a small selection of direct quotes within the notes. This analysis does not provide any quantification of how many patients mentioned each of the themes. Qualitative data collection methods are not designed with the aim of generalising findings to a wider population or about being representative, but they are about generating themes. Consequently, frequencies are misleading and not an appropriate way of representing the data. Quantification does not truly reflect whether others in the cohort experienced that phenomenon - only that they weren't asked directly about it to ascertain their beliefs. In order to understand frequency and the impact of these beliefs on behaviour, a quantitative study would need to be conducted.

5.6 Results

The BCFS team reported offering 118 patients KiActiv[®] Health, 46 (39%) contacted the company to find out more information or to enrol, 43 were recruited and 41 completed the 12-week programme (Figure 2) alongside the BCFS programme. Interest in joining KiActiv[®] Health was greater in patients with CFS/ME, than recruitment rates seen in people at medium or high risk of developing cardiovascular disease (CVD), and/or diabetes (Peacock et al., 2020). This suggests that patients with CFS/ME are eager to engage in discussions about their everyday movement. However, 73 (62%) patients chose not to participate in the KiActiv[®] offer, in favour of following only the BCFS programme. The reasons for this were not analysed.



Figure 2. KiActiv® programme participation rates

Patient characteristics

The 42 patients who started the programme were on average 38 years old (SD=15), 81% were female and their average BMI was classified as overweight (mean BMI = 26; SD=6; Table 1), a sample representative of the wider CFS/ME population.

Table 1. Patient characteristics

(Please note	e: all percent	ages have be	en rounded)
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	n	%
Sex		
Male	8	19
Female	34	81
Age (yrs)		
18-30	18	43
31-40	9	21
41-50	5	12
51-60	6	14
60-70	4	10
Deprivation decile by postcode (1=most deprived, 10=least deprived)		
3	2	5
4	1	2
5	3	7
6	9	21
7	6	14
8	7	17
9	5	12
10	9	21
BMI [≠] (kg·m ⁻²)		
Underweight (<18.5)	1	2
Healthy weight (18.5-24.9)	17	40
Overweight (25.0-29.9)	16	38
Obese (30-34.9)	5	12
Severely obese (35.0-39.9)	2	5
Morbidly obese (≥40.0)	1	2
Ethnicity		
White (British)	19	45
White (Irish)	1	2
Other (not stated)	22	52

* missing data for the one patient who withdrew

Adherence

On average, patients wore the physical activity monitor for 77 of the 84 days (92%) and 68 (80%) of these days were regarded as complete. Syncing of the device occurred on 43 of the 84 days (51%). Patients visited the KiActiv[®] online dashboard on 20 days (24%) and on 10 of these days (12%) patients also tagged their activities. Thirty-four patients (83%) chose to receive all five KiActiv[®] mentoring sessions, plus the set-up call.

Findings of a recent systematic review of cardiovascular patients estimates adherence to activity monitoring devices as being between 40% and 86% (Marin et al., 2018). This evaluation indicates that KiActiv[®] is able to engage and retain patients in wearing a device throughout the programme, and at a level greater than physical activity monitoring devices alone. This could suggest the added value of the personalised Mentor sessions and interactive online dashboard, in addition to the contemporaneous treatment interventions offered by the BCFS team. Of the 41 participants in this evaluation, 31 (76%) interacted with the technology beyond the initial 12-week period, either by visiting their personal online dashboard or syncing their physical activity monitor (i.e., uploading their data).

Patient impact

- 60% (n=15) of patients were more accepting of their fatigue
- 64% (n=16) of patients felt better able to pursue life activities regardless of their fatigue
- 48% (n=12) of patients recognised that avoidance and control are often unworkable methods of adapting to fatigue
- 60% (n=16) of patients gained greater awareness of how different activities could impact on their energy expenditure
- 54% (n=14) of patients became more confident in their ability to manage their daily activities in order to better use their energy levels
- 66% (n=23) of patients experienced an improvement in their overall health

Analysis of the quantitative data collected at the start and on completion of the programme indicated that patients with CFS/ME experienced a statistically significant improvement in CFAQ-8, EQ5D, awareness and confidence (Table 2).

Table 2. Change in patient-report outcomes from baseline to up to four weeks after the final mentor session

	Pre	Post	p
	m (sd)	m (sd)	
Fatigue acceptance ^a (n=25)			
Fatigue willingness	9.50 (4.40)	11.10 (6.1)	0.23
Activity engagement	10.30 (4.40)	12.10 (4.40)	0.03
Total score	19.80 (8.10)	23.20 (7.80)	0.05
Health status ^b (n=35)	47.00 (21.00)	59.00 (18.00)	<0.01
	n (%)	n (%)	
Awareness (n=26)			< 0.01
Strongly agree	6 (23%)	18 (69%)	
Agree	18 (69%)	8 (31%)	
Disagree	2 (8%)	0 (0%)	
Strongly disagree	0 (0%)	0 (%)	
Confidence (n=26)			<0.01
Strongly agree	0 (0%)	2 (8%)	
Agree	9 (35%)	17 (65%)	
Disagree	15 (58%)	7 (27%)	
Strongly disagree	2 (8%)	0 (0%)	

^a Chronic Fatigue Acceptance Scale 8; ^b VAS analogue scale from EQ-5D

Providing patients with accurate and comprehensive physical activity data in combination with the specialist clinical treatment given in the BCFS programme, also led to a statistically significant improvement in their awareness of what diminished and restored their energy levels (Table 2). In the qualitative data collected by KiActiv[®] Mentors, patients recognised how it had helped them to understand which of their day-to-day activities led to them using "too much" or "not enough" energy.

"You've helped me realise what's taking up most [of my] energy." (Female, 21yrs)

"I'm not sure what expectations I had, but yes because I've found it really, really useful. It's been good to have a tool that I can reflect on without me having to enter the information. I've done lots of questionnaires and they are all subjective, this isn't. It's a consistent, objective measure of what I've been doing." (Female, 57yrs)

"I've got something concrete to see where I use energy" (Female, 58yrs)

The Mentor notes showed how patients developed a better understanding of how everyday movement contributed towards their overall physical activity levels to support more effective pacing.

"I think it's really helpful to see what activities I am doing. It's just nice to see it. To show that even things that aren't exercise are activity." (Female, 23yrs) Alongside the specialised BCFS programme, patients used the visualisations found within the KiActiv[®] online dashboard, and the Mentor support, to create personalised goals and plans across the 12-week KiActiv[®] programme. These changed in response to their physical activity data. These goals, reported in the Mentor notes and patients' qualitative reports, ranged from moving more, and using this as a mechanism to lose weight and become fitter, through to rest and recuperation. The BCFS clinicians and Mentor notes depicted 'boom and bust' cycles, where energy expenditure was relatively high, followed by dips in physical activity and increases in sedentary time. This was often described within the context of worsening fatigue and a lack of pacing. These periods were often followed by patients setting goals with their Mentor, that aimed to move away from living in response to their fatigue - which often led to these periods of extreme activity and then crashes - towards a more consistent, planned approach to their everyday life.

"Yes it has, because it's helped me plan my activity and learn from when I'm doing too much, and I need to cut back." (Female, 34yrs)

Conversely, over the course of these combined interventions, patients and Mentors described more stable levels of fatigue, a consequence of setting strong intentions and having clear goals and action plans. These included breaking up strenuous activities and taking small regular breaks and, for some, doing more exercise as "*There's a certain amount of energy I need to expend to not feel tired*" (*Female, 23yrs*).

Patients valued the additional encouragement and support given by the Mentors and indicated that the sessions gave them the time and permission to reflect on their everyday lives in a person-led individually tailored way.

"The phone calls are really good as you have to be more accountable and pay attention and be more reflective. It's not just like you are using something that doesn't talk back to you, also the fact that there's a human involved, that makes it different to other things." (Female, 29yrs)

By helping patients to successfully pace, and with Mentors providing strong encouragement and support, in combination with the BCFS specialist treatments, patients experienced a statistically significant improvement in the confidence they had to manage their daily activities, and better use their energy, as well as their ability to pursue life activities regardless of their fatigue (Table 2). This meant feeling more accepting of their fatigue, realising that fatigue did not have to be controlled or the focus of all of their attention. This culminated in a statistically significant improvement in overall health and the expectations of KiActiv[®] being met or exceeded by 71% of patients (n=29).

5.7 Learning for potential future implementation and spread

It is important to acknowledge the impact of COVID-19 on patients, BCFS and implementation of KiActiv[®] Health, given that the project spanned much of the pandemic. For those who wished to engage in more traditional forms of physical activity, the pandemic did make this more difficult as a consequence of social distancing guidelines for people classified as clinically vulnerable or at increased risk of infection. Patients spoke about how COVID-19 had changed their living and working arrangements and caring responsibilities, making it difficult to pace and plan their activities. Patients reported periods of low mood related to this, which often led to increases in sedentary time and a decrease in calorie burn. Given that KiActiv[®] is an entirely virtual intervention, COVID-19 did not impact on the delivery of the programme. Adaptation in the delivery of the personalised comprehensive BCFS programme, from a group to virtual one-to-one sessions, also gave the BCFS team the opportunity to engage more in individualised discussions.

The qualitative data collected throughout this project enabled the evaluators to gather insights into the implementation and integration of KiActiv[®] Health, into the BCFS programme. Insights from patients and BCFS clinicians gathered during the course of the project were fed back into the project meetings, enabling adaptations to be made. Learning that came later in the project would be important to consider and address in any potential future spread of the innovation. These insights have been grouped to follow the initial introduction of KiActiv[®] Health to patients through to delivery.

Recruitment

- BCFS clinicians felt that KiActiv[®] Health was not appropriate for all patients. For some, this was because clinicians considered the use of this technology to be overwhelming for patients, and that patients had expressed a preference to use the hard copy BCFS Activity, Rest and Sleep Log. Others did not have the right technology or internet access or had significant cognitive fatigue or a learning disability that might prevent them from engaging in the KiActiv[®] programme. Having clear eligibility criteria, agreed between the innovator, clinicians and patients prior to beginning recruitment is key.
- Patients' prior values and behaviour are important factors to consider when introducing KiActiv[®] Health, along with understanding what support patients might need to successfully engage. Based on routinely collected qualitative assessment data, BCFS clinicians felt that those who gained validation and satisfaction from general everyday movement and being physically active before being diagnosed with CFS/ME, were particularly interested in participating. As were those who were more familiar with technology. Therefore, having a personalised and individual approach to uptake, depending on the circumstances and goals of the patient, was essential to recruitment and engagement with KiActiv[®] Health. This allowed them the choice to participate, as with other elements of the BCFS programme.

- Where BCFS clinicians were not familiar with KiActiv[®] Health, or where other clinical priorities arose during assessment, KiActiv[®] was not always introduced at the initial assessment appointment. This was accompanied by concerns that introducing KiActiv[®] at the assessment stage would increase the time of the initial assessment appointment, and the amount of information the patient was having to take on board, potentially at a point of diagnostic confirmation. This however, did not materialise and as the project progressed the introductory material became more embedded in the BCFS pathway. Integration of a prompt, or reminder, within the initial BCFS assessment could have improved this earlier.
- The knowledge and skills of the BCFS clinicians introducing the innovation, and the confidence to do so, was important to engaging patients in discussions about KiActiv[®] Health. Although questions about the innovation could be directed to the KiActiv[®] team, an additional training session delivered to BCFS clinicians' part-way through the project, increased clinician knowledge and confidence, and led to more referrals being made to KiActiv[®]. Future implementation should consider delivering sessions like this earlier in the embedding process, along with the provision of a wearable device for clinicians to use and experience.
- KiActiv[®] could be introduced to patients at any point in the usual care pathway from the BCFS initial assessment through to patients' six-month follow-up. However, earlier discussions, prior to being introduced to the BCFS Sleep, Activity and Rest Log seemed to be the most successful in terms of uptake.
- It was important to ensure that marketing materials were clear in regard to how
 patient data would be used by KiActiv[®], the distinction between KiActiv[®] Health and
 just physical activity monitors, and the overall aims of the innovation in the context of
 CFS/ME. Marketing materials were adapted early on in the project to address data
 usage concerns, and clarify that the project did not aim to increase physical activity
 in people with CFS/ME.

Delivery

- Clarity and agreement between all parties about how KiActiv[®] integrates and complements usual care is vital to potential implementation and engagement. Important aspects to consider in the context of BCFS were the timing and content of the BCFS programme sessions and KiActiv[®] Mentor sessions, to ensure there was optimal support. Having a clear rationale of how KiActiv[®] Health combines and potentially complements existing programmes and services is important. Some patients benefitted from using KiActiv[®] Health in combination with engaging in the evidence based BCFS programme, demonstrating value to integrating the two approaches.
- User-centred design is essential to the success of any innovation and has previously been an integral part of the development of KiActiv[®] Health. This unique pilot allowed the team to identify deeper insights into how the KiActiv[®] programme might meet the needs of people with CFS/ME.

 CFS/ME is characterised by fluctuating levels of fatigue, impacted by physical, as well as cognitive and emotional activity. Factors not specifically accounted for in the KiActiv[®] online dashboard.

"I was expecting to have something that was more tailored to me." (Male, 61yrs)

"I think that how it's designed it's not for someone with my condition. I've not got out of it what I thought I would get out of it. I haven't engaged in it as much as I thought I would. For me, that's a sign that it's not giving me what I need." (Female, 47yrs)

The focus on everyday physical activity in KiActiv[®] Health did enable some patients to recognise the importance of cognitive and emotional energy expenditure. Along with the space and opportunity to understand and explore the relationship between these factors, and how they can impact on symptoms of CFS/ME.

"It's given good insight into physical energy and because of that it's made me think a lot more about emotional energy." (Female, 22yrs)

"Being about to understand my activity in the way it has, has made me be able to look at the mental and emotional energy and give it the same attention as the physical." (Male, 47yrs)

Patients identified a number of ways in which KiActiv[®] Health could be adapted to better meet the needs of people with CFS/ME. This included greater alignment between the BCFS programme and KiActiv[®] Health, in terms of the presentation of data in the dashboard, and improving dashboard functionality by making it easier to distinguish between different types of sedentary activities. Clear messaging around the discretionary nature of the Mentor sessions during the project allowed those who struggled to find the energy to login use and engage with the online dashboard and Mentor sessions, to have a more tailored and considered approach to using the KiActiv[®] programme.

5.8 Conclusions

Are patients with CFS/ME willing to use KiActiv® Health?

In summary, approximately a third (n=43, 36%) of patients with CFS/ME who were told about the KiActiv[®] Health programme decided to enrol alongside the evidence based BCFS treatment programme. The demographic characteristics of the sample suggest that KiActiv[®] Health may attract patients with CFS/ME from across the spectrum, in terms of age, gender, deprivation and levels of obesity. Once recruited to KiActiv[®] Health, patients were highly adherent (n=41, 95%) and unlikely to drop out of the programme. For these patients, engagement in the mentoring sessions, wearing of the physical activity monitor, and syncing of the device, suggested that patients valued the innovation.

In-between mentoring sessions, and alongside the BCFS fatigue and lifestyle management programme, patients continued to log into the online dashboard and tag activities. This engagement continued beyond the 12-week KiActiv[®] Health programme.

What is the impact of KiActiv[®] Health on patients with CFS/ME, when combined with the BCFS treatment programme?

Twenty-five of the 35 patients (71%) with CFS/ME who responded, felt that their expectations of using KiActiv[®] Health had been met or exceeded. Alongside this, and in combination with the BCFS treatment programme, statistically significant improvements across a range of outcomes were reported. Despite changes in personal circumstances and, for some, the need to shield as a result of COVID-19, patients experienced a shift to a more positive view of themselves, their condition and overall health. Patients valued and recognised the importance of mentoring sessions and being able to visualise objective physical activity, which increased their awareness of how everyday movement could contribute to physical activity, along with what activities restored and reduced their energy levels. A small number of patients reported to the BCFS clinical team that they had chosen to use both the hard copy Activity, Rest and Sleep Log in addition to KiActiv[®] Health. recognising that the hard copy log allowed additional functions in terms of calculating baseline activity levels across all domains of physical, cognitive and emotional activity. Patients used the KiActiv[®] Health visualisations to create personalised goals, action plans and intentions with their Mentor. Together with the specialist clinical interventions provided by the BCFS team, this enabled participants to feel more confident in managing their dayto-day routines and successfully pace. This empowered patients to pursue activities that were important to them, whether this was everyday movement, such as gardening or cleaning, or more vigorous activities. As with other components of the BCFS programme, this evaluation suggests that KiActiv[®] Health could be offered as an integral part of a personalised approach to managing CFS/ME for some people.

What learning can we take from this project in order to potentially adopt KiActiv[®] Health, in combination with the BCFS treatment programme?

It is acknowledged that there are clear benefits to interventions delivered virtually, particularly during a pandemic. For those that signed up and engaged in the KiActiv[®] programme, the qualitative and quantitative data indicates positive effects on a range of outcomes. However, one of the primary barriers to recruitment was not having the appropriate technology platform or internet access. So despite the range in demographic characteristics of patients in this evaluation, the widespread use of KiActiv[®] Health may still be limited by the digital divide.

Once recruited, participant adherence with KiActiv[®] Health was high, but could be improved further if functionality across different platforms was enhanced, and further consideration was given to personalising the online dashboard for people with CFS/ME. This could include increased alignment with the BCFS programme and improving the method to record water-based activities, as well as cognitive and emotional energy expenditure.

Ensuring there is clarity and agreement about how KiActiv[®] Health could integrate with specialised personalised care, is an important factor when considering the potential application of the technology to other settings and patient groups. The BCFS clinicians saw opportunities to use the visualisations on the KiActiv[®] Health online dashboard with their patients, during the BCFS programme. Additional training would be useful, so that BCFS clinicians could make the most of these opportunities and better facilitate an integrated approach. BCFS clinicians showed enthusiasm for training and support from the innovator, which led to BCFS clinicians increased familiarity with the product, for potential user benefit. This could have been further enhanced by the provision of a monitor for each of the team members, which was not available.



6. KiActiv[®] adaptations

This project has demonstrated that the KiActiv[®] technology may contribute to helping patients to better understand and manage their physical energy, for the benefit of their condition, when used as an integrated supplement to specialist clinical interventions. The further insights gained during this project have provided the opportunity to build on this foundation and make some condition - specific adaptations, which may better address the complex biopsychosocial needs of this patient cohort.

Through analysing the patient feedback, and clinician feedback, KiActiv[®] has been able to draw out key themes for development, which would potentially enhance the usability and effectiveness, as a supplementary self-management tool in combination with specialist CFS/ME interventions. As a result of this, KiActiv[®] has begun scoping some adaptations which include general user interface (UI) and user experience (UX) upgrades, as well as improving the functionality to better capture and tag perceptions of energy use (physical, cognitive and emotional), how certain activities make patients feel, and self-reported quality of life measures. It will be important to do this in partnership with a specialist CFS/ME service, such as BCFS and expert user representatives.

7. Potential for the future and next steps

The Replenish-ME project is an example of a successful multi-partner real-world evaluation, that has provided an opportunity for a small number of people with CFS/ME to experience the KiActiv[®] innovation, in combination with the specialist BCFS programme.

The results from this evaluation indicate that the use of KiActiv[®] can have a positive impact, in combination with specialist CFS/ME provision. This project has identified a number of areas that would benefit from further exploration and development:

- Additional product development of KiActiv[®] technology in the areas that were identified during the Replenish-ME project, that were either limitations for this patient cohort, or that could improve patient experience.
- Further discussion with BCFS clinicians to understand whether there is a potential opportunity to continue exploring the integration of KiActiv[®] Health into their service, and the development of a commissioning case for this.
- The West of England AHSN business development team will continue to support KiActiv[®] to further explore opportunities for:
 - Cost-benefit evaluation
 - Development of a business case for CFS/ME
 - \circ Applications of this technology in the landscape of long COVID.

This project has provided an opportunity for effective collaborative working across NHS organisations and industry, resulting in key learnings for future partnerships.



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9. Appendix

Appendix A: A comment on heart rate as a measure of physical activity

Whilst a number of activity monitors have included a heart rate sensor, heart rate is limited in its accuracy and reliability. The rationale for using heart rate monitoring as a measure of physical activity or energy expenditure relies on the linear relationship between heart rate and oxygen uptake, which is only good for a narrow range of physical activity. While the linear relationship exists for specific activities, i.e., dynamic moderate to vigorous intensity activities involving large muscle groups (Crouter, Albright and Bassett, 2004; Freedson and Miller, 2000), the relationship between heart rate and energy expenditure is weak at low physical activity levels (Montoye, 1996). There are also a number of other individual factors that affect this relationship and getting a personalised understanding of this is a time consuming, labour-intensive, and expensive process, which is specific to the chosen physical activity modality (Eston and Reilly, 2001).

Another issue relating to the use of heart rate monitoring is the commonly used prediction of maximum heart rate [220-age], which has little scientific basis (Kolata, 2001). It assumes that regardless of any other factor (e.g., family background, height, weight, fitness level etc.) everyone has exactly the same maximum heart rate at a certain age, and that it goes down at exactly the same rate - by one beat on a specific day each year - no matter what has happened in the preceding 12-months (e.g., exercise training, illness, etc.). However, when researchers attempted to improve the accuracy of the formula, their data suggests that there is only a vague trend towards heart rate declining with age, and that even their improved equation could still over or under predict maximum heart rate, by around 20 beats per minute (Tanaka, 2001). A review of the formulas to predict maximum heart rate from age alone concluded that no such formula exists (Robergs, 2002). If the predicted maximum heart rate is inaccurate, any estimations made from it will also be inaccurate. Recent research indicates that heart rate, at the anaerobic threshold, is minimally influenced by the age of the person with CFS-ME. Concluding that heart rate formulae, generated to help people with CFS-ME undertake physical activity below this threshold, are unreliable and have a limited application in clinical practice (van Campen, Rowe and Visser, 2020).

Appendix B: Logic Model



Appendix C: Questions asked to patients and BCFS clinicians

Patients:

- 1) What are your expectations of using KiActiv[®] Health?
- 2) Has KiActiv[®] Health met your expectations? If so, in what ways? If not, why not?
- 3) What has helped or hindered you to use KiActiv[®] Health?

BCFS clinicians:

- 1) How have you found integrating KiActiv[®] Health alongside your programme?
- 2) What were your patients' experiences of using KiActiv[®] Health?
- 3) How has COVID-19 impacted your programme?
- 4) What were the barriers and enablers to implementing KiActiv[®] Health?

The Future Challenges

Keeping Healthy at Home: Replenish-ME

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