Detailed overview of the development of the Kidney BEAM intervention

Initial development phase

The initial development of Kidney BEAM included four iterative stages, which occurred rapidly over an intensive four-week period. Development was informed by the key principles outlined in the INDEX and DHI guidance. A diverse range of stakeholders were closely involved in coproducing the intervention throughout. These included fifteen expert researchers and clinicians with backgrounds in rehabilitation, physical activity, nephrology and digital health, five web developers, six partners from kidney charities (see Supplementary material 1 for details) and six stakeholders with expertise through lived experience of CKD (n=3, 50% male; 53 ± 17 years; n=3,50% White British; n=2; 33% pre-dialysis CKD, n=2, 33% dialysis, n=2, 33% transplanted). Whilst the shielding and lockdown restrictions imposed by the pandemic at the time precluded face-to-face interaction, the group met regularly using a series of meetings supplemented with the use of an online messaging app (Slack Technologies, LLC). The principles of co-production and participatory design for DHI were followed throughout. All perspectives were of equal importance and stakeholders shared the ability to make key decisions with the research team, with final recourse to the Chief Investigator.

1. Understanding the need

Whilst the restricted timescale for development prohibited any primary research during the development phase, existing and ongoing research relating to DHIs for physical activity was reviewed. Following this, barriers and facilitators to physical activity were reviewed and matched to the COM-B model within a behavioural analysis. ⁵⁻¹⁰ The COM-B model posits that three components need to be present for a behaviour to occur. These are: capability (the psychological and physical capacity to engage in the behaviour), opportunity (the physical and social factors that are conducive to the behaviour), and motivation (internal processes which influence decision-making and behaviours, including both reflective and automatic processes). ¹⁰ ¹¹

Several common barriers and motivators across all CKD stages and kidney replacement therapy modalities were identified from qualitative and survey data and these are

- 31 summarised in Table 2. Reflective motivation and physical opportunity occurred most
- 32 frequently, implying that facilitating the opportunity to become physically active and
- 33 leveraging behaviour change techniques to enhance planning and evaluation could promote
- 34 physical activity.

Table 1. Behavioural analysis: known barriers and facilitators to physical activity across CKD stages and kidney replacement therapy modalities

mapped to the COM-B model.

Barriers and facilitators to physical activity in people with CKD		Capability		Opportunity		Motivation	
		Psychological	Physical	Social	Reflective	Automatic	
Reduced mobility and function (perceived and actual) abe							
Symptoms arising from CKD and its treatment ^{abe}							
Presence of comorbidities and changes in health ^{ab}							
Lack of awareness of information about physical activity benefits and implementation ^{abcde}							
Lack of opportunity to be physically active due to the burden of treatment ^a							
Lack of opportunity to exercise due to catheter and vascular access ae							
Lack of accessible or suitable environments in which to exercise ^{abc}							
Lack of exercise equipment ^a							
Emotions (sadness, helplessness, anxiety) ^a							
Fears relating to safety (blood pressure stability, damage to vascular access, injury, exacerbation of condition/ symptoms, falls) abce							
Peer and family support for physical activity abcd							
Healthcare professional support for activity and prioritisation within CKD care ^{abc}							
Desire to improve physical condition, independence and maintain normality ^{abce}							
Observing improvements and achieving goals bcd							
Feeling guilty for not exercising bc							
Enjoyment of physical activity and choice bc							

- ^a barriers and facilitators to physical activity identified by people with end-stage kidney disease⁶; ^b barriers and facilitators to physical activity
- identified by people with pre-dialysis CKD⁷; ^{cd} barriers and facilitators to physical activity identified by kidney transplant recipients^{8 9}; ^e barriers
- 40 and facilitators to physical activity identified by people receiving peritoneal dialysis⁵.

2. Identification of intervention functions

Potential levers for change identified by the behavioural analysis were linked with intervention functions likely to be effective, using the Behaviour Change Wheel (BCW).

The BCW is a systematic approach which has been widely used to develop physical activity and rehabilitation interventions for people with long-term conditions.

The wheel links COM-B components to nine intervention functions, revealing appropriate strategies for supporting and maintaining behaviour change.

The following candidate intervention functions were identified: (i) training: imparting practical skills; (ii) enablement: increasing means / reducing barriers to increase capability or opportunity (iii) persuasion: using communication to induce positive or negative feelings or stimulate action; (iv) education: increasing knowledge or understanding; (v) incentivisation: creating an expectation of reward; (vi) environmental restructuring: changing the physical or social context; and (vii) modelling: providing an example for people to aspire to or imitate (Table 3).

These functions were then considered in relation to their affordability, practicality, effectiveness and cost-effectiveness, acceptability, safety and equity (potential for impact upon health inequalities), collectively known as the APEASE criteria. 10 Consideration of contextual fit was also key for Kidney BEAM to be readily implemented within the current NHS clinical landscape. Extensive engagement with NHS England, NHS Digital, Kidney Care UK, Kidney Research UK, The National Kidney Federation, the UK Kidney Association, the Chartered Society of Physiotherapy and the UK Kidney Research Consortium MedTech Group was undertaken to understand the current context into which Kidney BEAM would be implemented. This engagement highlighted the need for the online platform to meet the key Digital Technology Assessment Criteria (DTAC), including clinical safety data protection, technical security, interoperability and usability and accessibility standards. Compliance with these standards allowed for the consideration, and publication, of the Kidney Beam case study within the NHS Digital Renal Playbook. 12 During the pilot, Renal Getting it Right First Time¹³ was published and The Renal Services Transformation Programme¹⁴ initiated, which highlighted the need for holistic psychosocial and physical rehabilitation services, and this provided further opportunity to 'scale up' digital health interventions such as Kidney BEAM for greater national impact and future sustainability.

Intervention strategy used within Kidney BEAM	Behav	viour Change Technique		ervention actions	СОМ-В
Offer a range of physical activity classes and videos for people of different abilities and with different co-morbidities	• Ei in • M be	remonstration and instruction of the ehaviour via live sessions and videos ncouragement of practice via repeated nteraction and reminders Monitoring and feedback on the ehaviour elf-monitoring of the behaviour using the ctivity diary	•	Training	Physical capability
Provide accessible information about physical activity benefits, how to start and maintain a physical activity programme, specific to different stages of CKD and forms of kidney replacement therapy	• In ac	nformation about the benefits of physical ctivity and the effects of inactivity specific of CKD and related co-morbidities information/ specific physical activity dvice according to kidney replacement herapy modality	•	Education	Psychological capability
Offer physical activity options that can be done at home with minimal space and equipment	th • Id	estructuring the environment to remove he need for equipment dentifying items around the home that ould be used for resistance training	•	Enablement	Physical opportunity
Increase access to peer and healthcare professional support for physical activity	Oppl Socrettre cl	Opportunities to see peers undertaking hysical activity during live classes ocial support during class from peers and redible healthcare professionals, and in he education, sessions following a live lass eer support groups	•	Modelling Enablement	Social opportunity
Address beliefs about the influence of physical activity on symptoms and comorbidity	• In	nformation on common symptoms in CKD e.g., fatigue) and how physical activity	•	Education Enablement Persuasion	Reflective motivation

	might influence this delivered by credible sources (HCPs and people with CKD) Information on common comorbid conditions and the influence of physical activity Problem-solving and action planning for physical activity barriers Self-monitoring via the physical activity diary Sharing of experiences around symptoms and comorbidity between peers during live classes	
Address beliefs about the ability to be physically active with mobility and functional restrictions	 Information on current physical activity guidelines Information on the benefits of physical activity specifically for those with low levels of functional ability, delivered by credible sources Support and options via video and live classes for people with lower levels of ability or functional restrictions Demonstration of behaviours and linked back to tangible functional benefits Ability to observe peers during a live class 	Reflective motivation
Provide feedback on improvements in physical condition	 Feedback via diary and the assessment process Support participants to undertake SMART goal setting Self-monitoring of progress with goals 	Reflective motivation
Provide support to deal with challenging emotions arising from living with CKD	 Peer support groups Kidney psychotherapist/counsellor-led groups 	Automatic motivation

Address concerns relating to the safety of physical activity	•	Information regarding common fears relating to physical activity, delivered by credible sources Feedback on technique and suitable progression within live classes	Education Persuasion Modelling	Automatic motivation
	•	Demonstration of safe techniques via video and during live classes		

3. Identifying content and implementation options

Identified intervention functions were then linked to appropriate behaviour change techniques (BCTS) using the behaviour change taxonomy. ¹⁵Appropriate BCTS were selected by the stakeholder group based on the APEASE criteria, ¹⁰ their existing evidence base and whether the selected BCT was appropriate for use within a DHI. Intervention functions and their linked BCTs are outlined in Table 3. A logic model outlining the proposed mechanisms by which Kidney BEAM influences intermediate outcomes and long-term goals (HRQoL) is outlined in Figure S1.

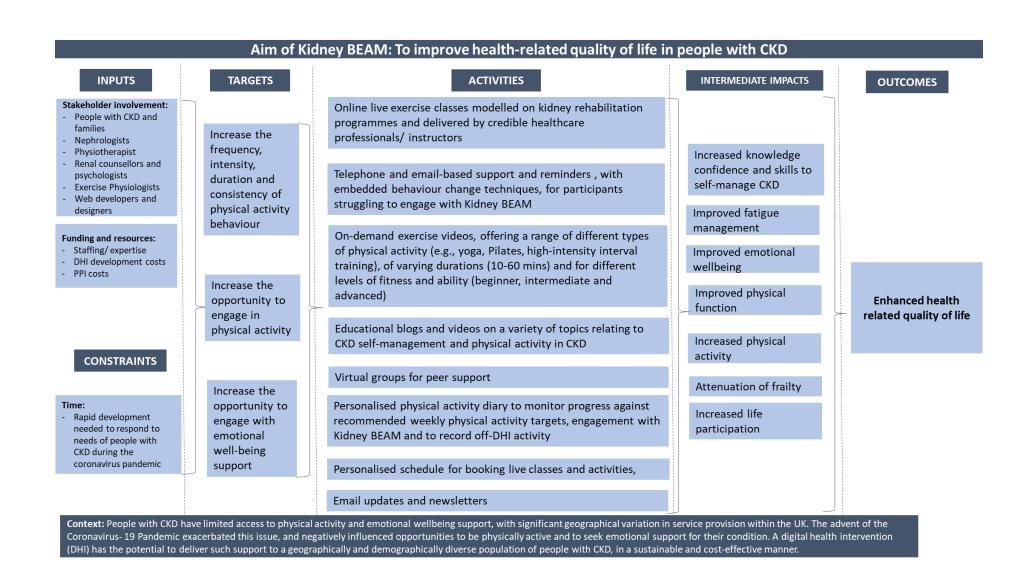


Figure S1. Logic model for Kidney BEAM.

4. Design of the Kidney BEAM DHI

Having identified the key functions of the Kidney BEAM programme and selected appropriate BCTs, a creative design phase began. This combined participatory co-design⁴ with user-centred agile software design¹⁶ to rapidly create an intuitive and engaging DHI, which had a high potential for effectiveness.

With the support and input of user experience (UX) designers, the stakeholder group generated ideas and made decisions regarding how the intervention functions could best be operationalised and delivered via a DHI. A user-centred agile design approach was selected to allow for rapid high-quality development, whilst also integrating the needs of end-users throughout. To this end, extensive up-front design was avoided, and instead, functionality was developed incrementally, whilst tangible 'mock-ups' and wireframes were initially used to gather feedback and iteratively design Kidney BEAM. These short incremental and iterative feedback cycles were used to make ongoing enhancements, progressing early prototypes towards a minimally viable product ready for more extensive user testing. Parallel design and development tracks were used, with design activities starting one sprint ahead of development activities.

Throughout the design phase, the needs of those with low literacy (including health and digital literacy) were considered and integrated to enhance accessibility. This resulted in the creation of 'how-to guides' as well as the provision of supplementary telephone and in-person support, for people requiring technical help. A partnership was formed with the digital inclusion charity Citizens Online¹⁷ to provide skills training and support access to Kidney BEAM. The charity also supported people to use Microsoft 'Edge Translate', a digital translation tool for online resources. Written content was checked for readability and the use of lay language throughout and was made available in large font.

User testing phase

At the end of the four-week initial development phase, there was a six-month user testing phase to assess how engaging the intervention was, and direct further refinement. This phase is reported in detail elsewhere, ¹⁸ but briefly, between 1 June 2020 and 30 November 2020 all people in the UK living with CKD aged ≥18 years were eligible to sign up. They completed a voluntary electronic survey on sign up which was repeated at six months, to establish whether they met current PA guidelines, investigate perceptions of health, and to collect usability and acceptability data. There were 959 sign-ups to Kidney BEAM in the 6 months. A pre-post survey revealed a 67% increase in people using Kidney BEAM meeting current national physical activity guidance of 150 minutes of moderately intense physical activity per week, a 20% increase in people reporting 75 mins or more of vigorous activity per week and 74% and 67% increase in number people meeting the twice-weekly strength training, ¹⁹ and who perceived their energy levels to be good or very good, respectively. More than 1.9,000 movement classes were completed during the 6 months, with a total of 60,000 movement minutes. Refinements included the addition of video content suitable for less mobile individuals (delivered in sitting).

The development phase ended after the six-months, to allow Kidney BEAM to be rapidly available to people with CKD during the COVID-19 pandemic and to commence formal evaluation as part of the Kidney BEAM trial.²⁰

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What were your impressions of Kidney BEAM when you first logged on? Did you join any of the groups on Kidney BEAM? Did you read any of the blog posts? One section of the site offers short educational videos on a variety of topics such as falls, goal setting and the benefits of physical activity. Did you watch any of these? Another section offers exercise classes 'on demand'. Did you try any of these? Intervention related topics Did you try any 'live classes? How often did you do an exercise programme per week? Did you upload any 'offline' physical activity into the diary on Kidney BEAM? What support was available to help you be more physically active? Was there anything that put you off using Kidney BEAM? How do you think we could improve Kidney BEAM in the future? How did you hear about Kidney BEAM? What made you decide to take part in the Kidney BEAM trial? How could we get more people to participate? Could you tell me about the process of signing up to this study? As part of this study there was a 50/50 chance of being put into the group which had access to Kidney BEAM immediately, or the other group who had to wait 12 weeks. How did you feel about this? As part of the study, you were asked to complete some assessments or tests to help the trial researchers understand if Kidney BEAM is effective or not. Trial related topics What did you think about doing these assessments online/ over the phone? What would help other people taking part complete these assessments/ tests? Some people may not manage to complete a research study like the one you have taken part in, which may happen for several reasons [give examples as

What would you like to happen once the study is completed?

needed].

Supplementary material 3. Demographics of those who declined to participate.

		N=166
Age (years)		58±15
Sex n (%)	Female	54 (33%)
	Male	112 (67%)
Ethnicity n (%)	White British	113 (68%)
	Asian or Asian British	27 (16%)
	Black or Black British	16 (10%)
	Other ethnic background	3 (2%)
	Information not provided	7 (4%)
CKD stage n (%)	Stages 1-5 (not receiving renal replacement therapy)	41 (25%)
	Haemodialysis	27 (16%)
	Peritoneal dialysis	27 (16%)
	Transplant	71 (43%)

Supplementary Material 4. Prioritisation of suggested amendments to Kidney BEAM prioritised according to MoSCoW

	MUST HAVE	SHOULD HAVE	COULD HAVE	WILL NOT HAVE	
Suggested amendment	Necessary	Important	Beneficial	Not a priority	Rationale
Provide more CKD stage and life stage specific content					Packages of CKD stage specific information added to kidney BEAM
Provide more detailed information for those who are not newly diagnosed.					Useful to have for participants who have had CKD for a longer-period of time, but will not influence engagement with the physical activity components of the intervention
Enhance ease of navigation via support and 'how to videos'					Essential to increase usability and simple to create and embed within the DHI on- boarding process
Highlight new content on the site					Provided as part of the telephone support and on-boarding process, but future adaptations may be made to support future implementation
Provide advice on the key aspects of Kidney BEAM to engage with					Provided as part of the telephone support and on-boarding process, but future adaptations may be made to support future implementation
Offer shorter physical activity options					Currently cost prohibitive but likely to be important for future implementation
Offer a more extensive live class timetable					Currently cost prohibitive but likely to be important for future implementation
Allow more leeway with live class bookings					Unable to change this as it is a safety requirement for the classes
Mandate more weekly engagement with Kidney BEAM					Would change the minimum amount of activity currently mandated within the trial protocol, but may be important for future implementation
Create text message reminders about booked classes					Functionality prohibitive and may be demotivating to some participants
Allow physical activity diary to be synced with wearable devices and provide personal summary analytics					Currently cost and functionality prohibitive but likely to be important for future implementation

Supplementary material 5: Script to support recruitment to the Kidney BEAM study.

Script for the BEAM study

- 1. Check you have right person on the phone
- 2. "Hi, my name is [name], I'm calling from [site]. It's nothing at all to worry about. I'm calling because [routine healthcare professional name here] thinks you might be interested in a study we are running, and I wonder if I might be able to tell you a little bit about it?"

If they agree...

- 3."We know that being more physically active is beneficial for people living with kidney disease. It helps to keep your blood pressure down, which can protect your kidneys from damage, and it can help keep you strong and independent, which is important for people with kidney disease because it can affect your muscles. It can also help boost your energy levels and help with symptoms like tiredness" {can tailor this to CKD stage}
- 4. "unfortunately we also know that not many people with kidney disease have access to any kind of help to support them to be more active. Because of this, we have developed a really lovely and unique online platform called Kidney BEAM which is especially designed for people with kidney disease."
- 5. "This platform gives you access to live and on-demand movement classes which are all led by specialist physiotherapists, or trained instructors who themselves are living with kidney disease.
- 6. "There is something on there for all levels of ability, so even if you haven't been active recently, or you are new to it, there will be something for you. The classes have a seated and a standing option so you can pick what feels right to you."
- 7. "There is also a range of different types of classes to try on demand, so if you have ever wanted to try Pilates, yoga, HIT or strength training you will find something to suit you."
- 8."The programme lasts for 12 weeks, and we hope people will use it twice a week. All the activity you do outside of the platform also counts towards this. You can do the classes live with the physio, or on-demand at any time which fits into your schedule."
- 6. "We are asking you to take part in this study because we want to see if this platform can help to improve people's mental and physical health"
- 7. "It's up to you if you decide to take part or not. If you don't want to then it won't affect any of the care you receive. Similarly, if you decide to take part and later decide to drop out, that's completely fine."
- 8. "If you do decide to take part I will ask for your email and send you a link to an online consent form. Once you fill this in you will have a 50/50 chance of either being in a group that has access to the platform right away, or one that waits 12 weeks and then has access. This is done randomly just so we can compare the effects of using the platform with not using it, but both groups will have access in the end. Being put into the group which has to wait doesn't mean that you aren't suitable to be more active."
- 7."You will be asked to take part in a brief assessment at the start of the study and at the end. These assessments are done online and will be arranged at your convenience, so there is no need to travel anywhere. We will ask you to fill in seven questionnaires and to do a sit-stand test. This involves

seeing how many times you can stand from a chair in 60 seconds and tells us about your strength. We will also ask for your permission to look in your medical records and to look at recent blood tests you may have had. We won't ask you to have any additional blood tests. "

- 8. "We are also asking some participants to take part in an interview online or over the phone. This is just to find out what you thought of the platform and how we might improve it in the future. The interview will be audio recorded and everything you say will be anonymised. If we use any quotes from you, you won't be personally identifiable. The interview is also optional, so you don't have to take part in this if you don't want to. "
- 9. "The benefits of taking part are that it might help you to feel better, to improve your fitness, strength, and physical health. You will also be helping to improve care for future generations of people with kidney disease." [can be tailored to the participants aims]
- 10. "The potential risks of taking part are the same with any type of activity programme. There is a small risk of injury for example pulling a muscle. We have tried to reduce this as much as possible by ensuring the classes are run by trained specialist physiotherapists and ensuring that you have an assessment beforehand. We have also checked with your doctor that you are suitable to take part beforehand."
- 11. "Do you have any questions for me? What do you think? Would it be ok for me to send some written information out to you by email? This just outlines what I have talked through today."
- 12. If yes collect and record email on spreadsheet. Send them out the PIS with the template email. Explain that you will call them back in a few days to see if they have any questions and to see whether or not they would like to take part.
- 13. If no thank them for their time