

Exploring How the Kidney BEAM Physical Activity Digital Health Intervention Improved Mental Health-Related Quality of Life for People Living With Kidney Disease: a Mixed Methods Approach

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Introduction: The Kidney BEAM randomized controlled trial reported clinically meaningful and statistically significant improvements in mental health-related quality of life (HRQoL), physical function (sit-to-stand-60, but not the physical component of HRQoL) and patient activation after a 12-week physical activity digital health intervention (DHI). This study explores factors that contributed to the effectiveness of Kidney BEAM through mixed methods analyses.

Methods: Quantitative data analysis was obtained from the recently published primary manuscript. Participants from the Kidney BEAM trial intervention group (n=30) completed individualized semistructured interviews after the 12-week DHI. Interviews were analyzed using the framework method with inductive and deductive coding. Quantitative and qualitative data collection and analyses occurred concurrently, and independently, before combining using a mixed methods analysis with joint displays to triangulate datasets and further explore the primary findings.

Results: The integrated mixed methods analyses facilitated explanation of the primary findings. The Kidney BEAM intervention was shown to have mental and physical wellbeing benefits and enhanced self-management in this cohort of people living with chronic kidney disease (CKD). Elements that contributed to the effectiveness of the intervention were reported, including the different functional levels and gradual progression of the program, shared lived experiences with other participants, self-monitoring, the sense of achievement, taking back control of their health, moving beyond medications, and feeling safe and confident to exercise.

Conclusion: Elements of the Kidney BEAM intervention that contributed to the main quantitative trial findings were identified. This will allow researchers and practitioners to maximize the effectiveness of DHIs to enhance healthy behaviors in people living with CKD.

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Despite recommendations to provide support for physical activity and emotional wellbeing interventions for people living with CKD, 1-3 access to specialist allied health professionals to support these behaviors is not routinely provided in the United Kingdom (UK), 2,4-6 and other countries.

Since 2019, there has been a rapid increase in DHIs and telemedicine across health care⁷⁻⁹ and specifically within kidney care. ^{10,11} A recent Delphi survey¹² from the Global Renal Exercise Group reported that people living with CKD wanted individualized and engaging exercise interventions, with a holistic approach. Given the lack of kidney-specific health care professionals, ⁴ and the need for holistic individualized care, ^{3,12} DHIs have the potential to address this gap in care, by providing remote self-care interventions that are deliverable at scale and at low cost while remaining patient-centered and accessible. ^{8,9}

A qualitative study¹³ conducted in 2 large CKD clinics in the UK reported on perceptions of physical activity, and motivators and barriers for DHIs to enable exercise interventions. The most discussed technology barrier was that the majority of applications appeared to be made for healthy people and did not address the need for confidence and skills to support people living with CKD to be physically active, particularly in the long-term.¹³ In addition, DHIs need to be easy to use, and flexible to the needs of someone living with CKD who may experience changing energy levels, comorbidities, and health status.¹³

The Kidney BEAM trial was conducted to explore the clinical value and cost effectiveness of a physical activity DHI for people living with CKD. 14 To our knowledge, Kidney BEAM was the first robust trial to report the positive effect of a physical activity DHI on HRQoL. Digital innovations such as Kidney BEAM provide a scalable option to deliver a kidney-specific physical activity intervention. 14,15

Our published methods manuscript ¹⁶ have described the aims and objectives of the main trial, ¹⁴ and the qualitative interviews presented in this mixed methods manuscript. In summary, the qualitative interviews aimed to explore the participants' experiences of using the Kidney BEAM DHI, its impact on living with CKD, and contextualize the results of the main trial ¹⁴ utilizing mixed methods analyses. ¹⁶ This mixed methods manuscript reports on the quantitative data and the qualitative data, and presents the mixed methods

analyses to facilitate an enhanced understanding of why the treatment led to the observed results. More generally, these findings will allow researchers and practitioners to maximize effectiveness of DHIs to enhance healthy behaviors in people living with long-term chronic conditions such as CKD.

METHODS

This manuscript is informed by qualitative research reporting guidelines (Consolidated criteria for reporting qualitative research, [Supplementary Table S1])¹⁷ and relevant CONSORT extensions. ^{18,19}

Study Design

The Kidney BEAM trial was a prospective, mixed methods, multicenter randomized waitlist-controlled trial. The methodology and results are reported elsewhere. 14,16,20 In summary, the trial recruited 340 participants living with CKD (n = 173 Kidney BEAM intervention and n = 167 waitlist control group; 1:1 randomization) from 11 sites across the UK. The Kidney BEAM intervention 14,16,20,21 can be categorized as a complex DHI intervention, with many interconnected components²² that extend beyond exercise (including online exercise sessions, telephone and email support, education sessions, self-management, peer support, self-monitoring and personalized scheduling). 14,16,20,21 Exercise is delivered via the DHI by either live group classes or recorded sessions participants could complete individually. In total, 24 sessions were offered over the 12-week trial period. 14,16 Each exercise session (approximately 40 minutes) consisted of a graded warm-up, conditioning, and cool-down phases. 16 Outcomes were assessed at baseline, 12 weeks, and 6 months. 14,16 Ethical and regulatory approval was obtained from the Bromley National Health Service Research Ethics Committee and the Health Research Authority (reference 21/L0/0243), respectively. The trial was preregistered (www.clinicalTrials.gov; no: NCT04872933).

This manuscript reports the quantitative results from the primary manuscript (n = 340), ¹⁴ in addition to new data from the qualitative analysis of the semi-structured interviews (n = 30) with intervention participants. Integrated mixed methods analyses were then used to explore the primary findings.

Setting, Recruitment, and Participants

Eligibility criteria for the main randomized controlled trial ¹⁴ have been reported elsewhere. ¹⁶ In summary, people aged ≥18 years living with all types of CKD, willing to take part in the Kidney BEAM trial, and able to speak English were considered. Potential participants were excluded if they were unable to exercise safely, ²³ had a body weight <50 kg, had previously participated in a structured exercise intervention or Kidney BEAM within the last 3 months, or were unable to consent. ¹⁴

Thirty participants from the main trial sample, specifically focusing on those who had been randomized to the Kidney BEAM intervention (n = 173) were purposively sampled and invited to interview by phone at their 12-week reassessment visit (after completion of the Kidney BEAM program) to minimize recall bias. As described in our methods manuscript, 16 interview participants were purposively sampled for maximum variation to ensure diversity across the sample.^{20,24} The predetermined sampling framework included ethnicities, age, sex, stages of CKD as determined by eGFR,²⁵ history of renal replacement therapy or not (e.g., dialysis), study site location, and intervention adherence levels. 16 Data quality and richness was ensured by the pragmatic model of "information power," which has an inverse relationship with sample size in qualitative research. 26,27 Information power, and therefore sample size, is influenced by the study aims, specificity of the sample, the existence of theory, the quality of communication between the researcher and participant, and the analysis strategy. 26 An a prioridetermined sample size of n = 30 was deemed sufficient to achieve information power and address the aims of the study. 16,20,26 Our study had specific aims, with a specific sample (those completing the Kidney BEAM intervention), based on theory, with interviews conducted by experienced researchers. Interviews were conducted by using telephone or remotely using online software depending on participant preference. Interviews were conducted by a team of experienced qualitative researchers (EMC, REB, JB, CW, and HMLY) (Supplementary Table S2).

Analyses

Quantitative Analysis

Outcomes were analyzed by an intention-to-treat approach utilizing an analysis of covariance model, with baseline data and age as covariates to determine the between-group mean difference at 12 weeks. ¹⁴

Qualitative Analysis

People with lived experience of CKD from the patient and public involvement group, and experts from the trial steering group reviewed and provided feedback on the topic guide (Supplementary Figure S1) and qualitative methodology. The qualitative methods used across the pilot phase of the trial, the results of which are described elsewhere, 20 and the analysis described in this paper which contextualizes and expands on the results of the main trial, are outlined in detail in the methodology paper.16 Briefly, all individual semistructured interviews were audio recorded, anonymized, transcribed verbatim, and imported to NVIVO (Version 12 for PC, QRS International, MA) as a data management tool. Data were analyzed using the framework method, which supported the identification of both inductive codes derived directly from the dataset, and deductive codes based on the RE-AIM framework (reach, effectiveness, adoption, implementation, and maintenance)16,20,28-30 The results of this paper primarily focus on the "effectiveness" component of the RE-AIM framework, in order to understand and expand upon the results from the main trial. A pragmatic philosophical standpoint 31,32 was utilized, where the best methods are used to answer the research question. Information power²⁶ was revisited after the first 3 interviews and during the analyses.³³ Reflexive journaling, and meetings with the qualitative and wider research team, were utilized throughout to ensure rigor and reflexivity, discuss codes and their definitions and to finalize a coding framework, which was then systematically applied to the data.

Mixed Methods Analyses

A convergent mixed methods analysis was used,³⁴ where quantitative and qualitative data collection and analyses occurred separately and simultaneously before being integrated within a joint display.^{34,35} In Supplementary Figure S2, we summarize the overall Kidney BEAM project and contextualize the mixed methods analyses. The primary findings from the recent main manuscript¹⁴ were explained through mixed methods analysis.

RESULTS

Quantitative Results

Quantitative results reported in the primary manuscript are summarized below. Intention-to-treat analysis revealed statistically and clinically significant improvements in the primary outcome, the difference in the Kidney Disease Quality of Life Short Form version 1.3 Mental Component Score (KDQoL-SF 1.3 MCS). There were statistically and clinically significant improvements in the following secondary outcomes: the social function and energy/fatigue subscales of the KDQoL-SF 1.3, physical function (demonstrated by the STS60 test), and patient activation (measured by the PAM-13). The following secondary outcomes did not

demonstrate statistically significant improvements on intention-to-treat analysis: other components of the KDQoL-SF 1.3 (the physical composite score [PCS]), burden of kidney disease, and general health), self-reported physical activity, fatigue, impaired functioning, the European Quality of Life 5 Dimensions 5 Levels questionnaire, and the measurement of mood and anxiety (Table 1).

Qualitative Results

Thirty-four Kidney BEAM intervention group participants were approached, of which 30 agreed to complete qualitative interviews. Baseline characteristics are summarized in Table 2. Stages of CKD were defined as per UK Guidelines.²⁵ Interviews were conducted between April 19, 2022, and March 21, 2023.

Qualitative Findings

Three major themes relating to exploring the effectiveness and experiences of the Kidney BEAM intervention were constructed from the qualitative data. These explained both the effects seen by participants, as well as the contributory factors and components of the intervention, which participants felt led to these effects. These themes are the following: (i) fostering a positive mindset; (ii) strength, fitness, and activity for everyday life; and (iii) discovering new knowledge and skills, to support a more holistic approach to self-management

A thematic map is depicted in Figure 1. A summary of each theme, with illustrative quotes is shown in Tables 3, 4, and 5, respectively.

Theme 1: Fostering a Positive Mindset

Most participants completing the Kidney BEAM intervention reported a shift toward a more positive mindset. They voiced improvements in mood, and the release of endorphins (Table 3). However, a few participants felt they had positive mental health before commencing the intervention, and therefore they did not anticipate any changes.

Participants attributed this positive mindset to shared lived experience with other people living with CKD, self-monitoring their use of the Kidney BEAM intervention (the number of sessions completed, the amount of physical activity completed), and subsequently gaining a sense of achievement and desire to do more. Though participants described the positive effect of peer support via the intervention, a few participants preferred to exercise independently using the recorded sessions. One participant in isolation felt "judged" by other participants in the live class. Overall, the education program, and discussions with other Kidney BEAM users was valued above the health care professional perspective. Choice in delivery (group live class vs. independent recorded class),

and peer support appeared to be important considerations for Kidney BEAM participants.

Self-monitoring, including checking the number of sessions completed, and overall physical activity levels, fostered internal motivation and self-efficacy. Most participants suggested that once they started completing sessions, they experienced enhanced motivation. Achieving sessions, increased their confidence and desire to complete furthermore, and subsequently the 12-week Kidney BEAM intervention.

Theme 2: Strength, Fitness, and Activity for Everyday Life

All participants reported some form of physical benefit from taking part in the intervention. The main physical benefits reported were an improvement in aerobic fitness and endurance, strength and the ability to perform activities of daily living, and reductions in symptoms (particularly pain and fatigue) (Table 4).

Some participants reported increasing their daily physical activity levels as a result of completing Kidney BEAM. In contrast, others reported substituting previous physical activity such as walks with Kidney BEAM, thereby replacing habitual physical activity with structured exercise training. Other participants reported no change to physical activity levels because they felt their physical activity levels were already sufficient.

There were 2 key suggested reasons for the physical benefits described above. These were the fact that the Kidney BEAM intervention was inclusive, enabling anyone to participate in the exercise sessions, and building their confidence. Participants specifically highlighted the importance of having 2 instructors in each Kidney BEAM session who provided seated and, standing options.

Alongside the progression from sitting to standing participation, another key factor for the physical benefits was the gradual progression in difficulty from the start to the end of the 12-week Kidney BEAM program. Participants were able to see improvements in strength, fitness, physical symptoms and daily life as they progressed through the 12 weeks.

Theme 3: Discovering New Knowledge and Skills to Support a More Holistic Approach to Self-Management

Not all participants made a clear distinction between their physical and mental wellbeing. The new knowledge and skills gained from taking part in the exercise sessions and educational content contributed to participants' overall wellbeing. Participants described how the intervention provided them with new knowledge and skills to self-manage their condition, which they had not consistently received elsewhere in their routine kidney care.

Table 1. Joint Display combining QUANT and QUALI datasets for mixed methods analysis

Concept being assessed	QUANT outcome Result (mean difference between groups (95% CI) from ITT analysis)	QUALI Themes and their meaning	Mixed methods inferences (partially agree, agree, discordance or expansion)
Health-related QoL and sub-scales	KDQoL MCS (AU) +3.1 (1.8-4.4), P < 0.001°	Most participants voiced an improved sense of mindset, mood, and emotional wellbeing. Peer-support, self-monitoring, and a sense of achievement were suggested reasons for the mental wellbeing benefits experienced. In contrast, few participants reported that their mental wellbeing was already strong before starting the intervention. Some participants mentioned viewing wellbeing as a combined mental and physical concept.	† ¶
	KDQoL PCS (AU) $-0.7~(-2.0~{\rm to}~0.7),~P=0.35$	All interview participants ($N=30$) expressed some form of physical benefit. This was thought to be due to the accessibility of the Kidney BEAM platform for different functional abilities, and the gradual progression of intensity and difficulty within the Kidney BEAM intervention.	§
	KDQoL Burden of Kidney Disease (AU) $+3.2$ (0.0-6.4], $P=0.049$	Participants report being able to self-manage and learn about their condition while taking part in the Kidney BEAM exercise and education sessions.	‡
	KDQoL General Health (AU) -0.8 (-3.4 to 1.8), P = 0.558	Interview participants revealed improvements in mental, physical and combined wellbeing (all themes).	§
	KDQoL Social Function (AU) 4.4 (0.9–7.8}, $P = 0.013^{\circ}$	Qualitative reporting suggests peer support, and support from the physiotherapy instructors as social aspects contributing to the effectiveness of the Kidney BEAM intervention. Some participants were surprised by how much they enjoyed the peer-support element of the Kidney BEAM package. Others expressed Kidney BEAM was their main source of socialization.	† ¶
	KDQoL Energy/Fatigue (AU) $+7.0$ (4.6–9.5), $P < 0.001$ $^{\circ}$	Physical fatigue was shown to improve in interview participants. This was felt to be due to the gradual progression and different levels of functional ability demonstrated during the Kidney BEAM classes.	‡
	EQ-5D-5L Utility score (score) $+0.01$ (-0.02 to 0.04), $P=0.64$	All qualitative data suggests improvements in mental wellbeing, physical wellbeing and combined wellbeing and suggests reasons for these.	§
Fatigue	CFS (AU) -0.5 (-1.5 to 0.5), P = 0.33	Physical fatigue was shown to improve in interview participants.	‡ ¶
Physical function	STS60 (reps) $+3.8 (2.6-4.9)$, $P < 0.001$ $^{\circ}$	All participants expressed some form of physical benefit from taking part in the intervention. Participants reported feeling fitter and stronger, improved symptoms such as fatigue, improved functional activities such as sit-to-stand and improved strength. QUALI data expands knowledge. The different levels of functional ability and gradual progression within the Kidney BEAM program were suggested reasons for the physical benefits gained.	† ¶
Patient activation (Knowledge, skills, and confidence)	PAM-13 (score) +6.9 (4.9-8.8), <i>P</i> < 0.001°	The significant change in PAM can be expanded through QUALI data. Participants expressed new knowledge and skills, a sense of ownership and taking back control of their health and CKD management, the promotion of self-management, and shifting away from traditional medical paternal models to self-management and empowerment. Peer support from loved ones and feeling safe and confident with exercise further support this shift.	† ¶
Depression and anxiety score	PHQ4 (score) $-0.4 (-0.8 \text{ to } 0.5), P = 0.082$	QUALI data suggests some general mental wellbeing benefits such as feeling better and a more positive mindset. Few participants report no improvement in mental wellbeing and mood given that they report good baseline levels.	§ ¶
Work and social adjustment score to assess work, social, relationships and private leisure	WSAS (score) +0.4 (0.8-1.7), P = 0.491	Some participants report that support from family members and loved ones helped them implement the lifestyle changes from the Kidney BEAM intervention.	‡
Physical activity	GPAQ (METS/min/wk) 393 (-334 to 1120), P = 0.288	Some participants express improvement in PA levels, some report no change due to already good baseline levels, and others report Kidney BEAM replacing another PA.	§ ¶
	GPAQ (PA min/d) 14.0 (-11.9 to 40.0), $P = 0.288$	See row above	† §

AU, arbitrary units; CFS, Chalder Fatigue Scale; CI, confidence intervals; EQ-5D-5L, European Quality of Life 5 Dimensions 5 Level Version; GPAQ, Global Physical Activity Questionnaire; ITT, intention-to-treat analysis; KDQoL, Kidney Disease Quality of Life; MCS, Mental Composite Score; METS, Metabolic Equivalent; PA, physical activity; PAM-13, patient activation level 13; PCS, physical composite score; PHQ4, patient health questionnaire 4; QoL, Quality of Life; QUALI, qualitative; QUANT, quantitative; STS60, sit to stand 60 seconds; WSAS, work and social adjustment scale.

^aStatistically significant.

Note: † indicates agreement, ‡ indicates partial agreement of datasets, § indicates discordance, ¶ indicates expansion of knowledge.

Kidney BEAM was viewed as a vehicle for connecting the mind and the body. Physical and mental wellbeing appeared connected and influenced each

other, with participants indicating that Kidney BEAM helped both their mood and their wellbeing, and their physical health and physical activity. For example, 1

Table 2. Demographic and clinical characteristics of the qualitative participants (n = 30)

Variable	Additional details	n = 30
Age (yrs) ^a		55 (44-67)
Sex, n (%)	Female Male	13 (43%) 17 (57%)
Site, n (%)	Portsmouth Leicester Devon & Exeter King's College Hospital London Guy's & St Thomas' Hospital London Derby Barts Preston Nottingham Salford Royal Free	1 (3%) 3 (10%) 3 (10%) 1 (3%) 5 (17%) 6 (20%) 4 (14%) 1 (3%) 4 (14%) 1 (3%) 1 (3%)
Ethnicity, n (%)	White British Asian or Asian British Black or Black British Mixed background	20 (66%) 3 (10%) 5 (17%) 2 (7%)
Estimated glomerular filtration rate at baseline ^a (eGFR measured in ml/min per 1.73 m ²)		41.5 (20.8–57.3)
	Receiving hemodialysis Receiving peritoneal dialysis Kidney transplant recipient Not receiving hemodialysis, peritoneal dialysis, or a having an active kidney transplant	4 (13%) 1 (3%) 7 (23%) 18 (61%)
Number of Kidney BEAM sessions completed ^a		15.5 (10–21)
Adherence categories, n (%)	Very high (more than 24 sessions) High (18–24 sessions,	5 (17%) 6 (20%)
	75%-100% adherence) Moderate (12-17 sessions, 50%-74%)	10 (33%)
	Low (<12 sessions, <50%)	9 (30%)

CKD, chronic kidney disease.

Table values reported are mean and SD (\pm) , except for ^amedian and IQR. All participants were invited to interview after completion of the 12-week study visit (and Kidney BEAM intervention).

participant mentioned that the exercises made it easier on their body but also their mind and emotions.

These combined wellbeing benefits were explained by the participants "taking back control" of their health, moving beyond the traditional medical model of medication-focused care, and building confidence in exercise. Through increasing their knowledge and skills, and overall wellbeing by taking part in Kidney BEAM, participants felt they could more actively engage in their self-management of CKD. Participants sensed a change from the passive paternal medical model to a more shared treatment approach.

Kidney BEAM focuses on holistic aspects of care through exercise and education. This made participants feel that managing their CKD was not limited to taking medications, it was also about taking care of themselves, and their lifestyle, such as exercise, and non-pharmacological management.

Through both the specific knowledge of exercising with CKD conveyed by the Kidney BEAM exercise

professionals, and the practiced skills of regularly taking part in supervised, progressive, and supported virtual exercise, the participants reported an improvement in confidence and self-efficacy to participate in exercise sessions.

Mixed Methods Analyses

The integrated mixed methods analyses facilitated explanation of the primary findings recently published. The Kidney BEAM intervention was shown to have mental, physical, and combined mental and physical wellbeing benefits in this cohort of people living with CKD. The reasons for these benefits are suggested by interview participants (Figure 1, Tables 3, 4, and 5). Table 1 demonstrates the joint display and the mixing of the qualitative and quantitative datasets.

The mixed methods analyses allowed for exploration and postulation of reasons for the clinically and statistically significant findings of improved mental HRQoL (KDQoL MCS), patient activation (PAM-13), and physical function (sit-to-stand 60) in the primary manuscript. 14 There was strong agreement between the quantitative and qualitative datasets for these outcome measures. Partial agreement was realized between the qualitative and quantitative datasets for measures of fatigue (CFS, Energy/ Fatigue subscore of KDQoL), work and social adjustment, and the burden of disease (subcomponent of the KDQoL). Discordance between datasets occurred between the quantitative intentionto-treat data and the qualitative data sets for the following outcomes: the physical composite score (subscore of the KDQoL), the general health subscore (of the KDQoL), the European Quality of Life 5 Dimensions 5 Levels measure, self-reported physical activity, and self-reported anxiety and depression scales. The integrated analyses results have allowed the original logic model²⁰ to be updated to reflect the mixed methods findings (Figure 2).

DISCUSSION

Summary of Main Findings

This work increases our understanding of the important elements of an effective DHI (Kidney BEAM) to improve mental-related quality of life for people living with CKD. The quantitative findings were extended by the qualitative analysis of a purposive sample of participants who engaged in the Kidney BEAM intervention and revealed 3 key themes exploring the experience and effectiveness (Figure 1). Key elements contributing to the improved mental, physical, and combined mental and physical wellbeing reported by the interview participants were the shared lived experience with other Kidney BEAM users, the selfmonitoring of progress, the building of motivation,

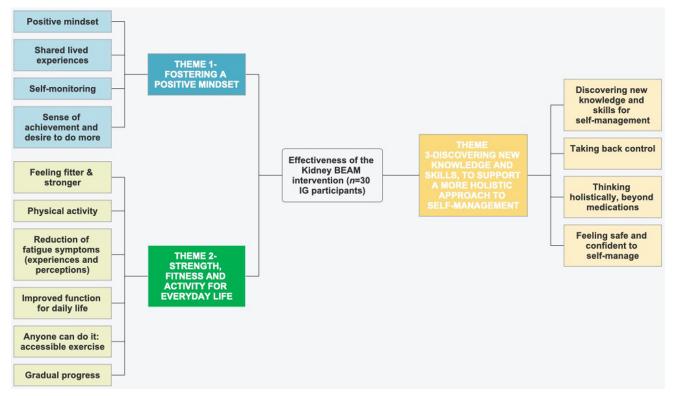


Figure 1. Thematic map exploring the 3 qualitative themes from the framework method. The main concept of effectiveness is displayed by the white rectangle at the center. The corresponding themes relating to effectiveness of the kidney BEAM (KB) intervention are depicted by the colored bold rectangle boxes, with their associated subthemes branching outward (Themes 1 to 6). Note the dotted lines between T1 and T2, T3 and T4, and T5 and T6 suggesting relationships. T, theme.

the choice in delivery (group live vs. individual recording), the inclusive nature of the program with sitting and standing options, the gradual progression, the new knowledge and skills obtained through exercise and education fostering self-management, self-efficacy, and patient activation. The integrated mixed methods analyses allow for exploration and postulation of the main findings of the trial previously published. ¹⁴

A key benefit of the Kidney BEAM intervention was the improvement in the primary outcome (MCS of the KDQoL)¹⁴ and the reported improvements in positive mindset. The integrated analysis facilitated explanation and expansion of understanding through patient-experience via the qualitative results. Participants revealed that shared-lived experience, self-monitoring and the sense of achievement, and desire to do more are the reasons for improvements in positive mindset and improved mental wellbeing.

Results from the mixed methods analyses suggest that contributing factors such as increased knowledge, confidence, and the skills to self-manage CKD may have led to the intervention effects on mental HRQoL. Shared lived experience from other Kidney BEAM users living with CKD was a key factor to the success of Kidney BEAM on mental wellbeing. Peer support has been utilized in other studies and is a recommended approach

in national programs.^{36,37} Peer support can lead to improved confidence, reassurance and acceptance, and enhanced self-management behaviours.^{38,39}There is growing evidence supporting the use of online groups for people living with CKD to provide information, support, and peer support both in the UK^{40,41} and in the USA.⁴² The results from this current study agree with these studies, with interviewed participants reporting value in peer support and shared experiences through participating in the group exercise program, and through engagement with the education component. A small proportion of interview participants reported preference in working individually on Kidney BEAM. This suggests a need to individualize programs to allow flexibility to meet different personal preferences.

Self-monitoring is a powerful behavior change technique and is recommended for physical activity and exercise DHIs,⁴³ and for DHIs for people living with CKD.⁴⁴ In the present study, participants used self-monitoring to review how many sessions they completed through the Kidney BEAM home screen portal, as well as their progress of physical activity on and off the Kidney BEAM platform. Participants reported that tracking their Kidney BEAM sessions and physical activity helped motivate them to continue with the intervention. Furthermore, completing a

Table 3. Illustrative quotes for theme 1: fostering a positive mindset

Subthemes		Illustrative quotes
Outcome	Positive mindset	"My overall feelings have probably improved. I think yeah, I think probably more positive in other areas now and don't feel quite so insulated." (Male, 76 yr, Stage 3a CKD) "I felt better from a mental perspective, you know, having a clearer mind and a bit more positivity, you know, because sometimes you can sometimes in the doldrums a little bit." (Male, 49 yr, Stage 3a CKD) "Just made it a bit better, my mental health. Yeah, it's just made it a bit better than what it was before starting this Kidney Beam program." (Male, 52 yr, Stage 5 CKD) "It's actually helped me with my mental health, so I don't see why others shouldn't have the access to something that may help them." (Female, 57 yr, Stage 2 CKD) Contrasting quotes "I don't really think it's had any effect. I think I did feel better when I was doing the sessions but, yeah, I don't think it really has much of an impact." (Female, 43 yr, Stage 4 CKD). "That's a really interesting question. In the same way that I don't dwell on things and let them get me down, I don't think doing this (Kidney BEAM) has necessarily raised the stakes or raised my motivation or raised my awareness or general mood." (Male, 67 yr, Stage 3a CKD) "No, it's (MWB) the same, as which is always pretty positive." (Female, 65 yr, Stage 2 CKD)
Factors and influences contributing to the outcome	Shared lived experience Self-monitoring	"I don't think you can beat talking to somebody who's got the problem." (Male, 76 yr, Stage 3a CKD) "For me it was fantastic really to see other people with the condition and how maybe they were managing it, and what sort of quality of life they had, you know. What were they able to do you know. How did they manage their did their symptoms affect their ability to have a good quality of life." (Male, 30 yr, Stage 2 CKD) "Some of us in the group, and actually we can learn from one another." (Female, 63 yr, Stage 5 CKD) Contrasting quotes "I did just because I'd rather just get on with it and I don't need to have any chitchat before or afferwards. It was for me and me alone, sort of thing." (Male, 68 yr, Stage 2 CKD) "The fact I could go on it anytime. I had the privacy. It was not rushed." (Female, 57 yr, Stage 2 CKD) "One of the good things about the website was seeing your progress, so how many units you've done, and the expectations of what you need to do, you become your own but yeah, it was good to be able to see that on the website, that was a real kind of motivator for me." (Female, 47 yr, Stage 3b CKD) "I think going in and doing the activity diary helps keep it present in your mind as well. So, to say to somebody you know, that's probably what I would say – that will keep you motivated, especially doing other things. It gives you the totals as well so it's kind of "Oh I've only done fifteen so far" you know what I mean – "I need to do some more." (Male, 65 yr, Stage
	Sense of achievement and desire to do more	3b CKD) "It motivated you because once you did one class you want to do the next and build." (Male, 49 yr, Stage 3a CKD) "But it was brilliant to have a structure where someone else is leading and just to be able to follow that for forty minutes and go "Oh my God, that's it, I've done it" and on a regular basis, then to feel the benefit." (Female, 57 yr, Stage 3b CKD) "Yeah, I mean, it's been a bit like, they call it like a hockey stick effect, so where you get a small momentum and the more exercise you do, I found with Kidney Beam, the more I want to do, but it's getting that ability to start that hockey stick kind of swing and start." (Female, 47 yr, Stage 3b CKD)

CKD, chronic kidney disease.

Kidney BEAM session, and progressing through the program lead to a sense of achievement, and further fueled their motivation.

Mixed methods analysis revealed improvements in objective physical function (via the STS60, an improvement of 3.8 repetitions, $P < 0.001^{14}$), and improvements in strength, fitness, and activity for everyday life. All interview participants reported some form of physical benefit, whether it be in fitness, strength, reduced physical fatigue, or improvement in functions required for daily life. The intervention was seen to be inclusive, achievable, and individualized to their needs. However, there was no significant improvement in the KDQoL PCS.

A potential reason for the improvement in STS60 but not in the KDQoL PCS could be because they measure different aspects of physical function. The STS60 is a measure of lower body functional capacity and is recommended for assessing physical function in people living with CKD. 45,46 The KDQoL SF1.3 has also been validated in people living with kidney disease 47; However, PCS is influenced by all 8 subdomains of the SF36, with self-reported physical function being only

one of these 8 subdomains. 48 Particularly, general health, bodily pain, and role-physical subdomains are weighted heavily. 48 Consequently, the KDQoL PCS can be more resistant to change than direct measures of physical function in response to exercise interventions, as evidenced by a multicenter randomized controlled trial evaluating intradialytic cycling compared to usual care, 49 and a meta-analysis suggesting questionable effects of exercise interventions on HRQoL in people receiving dialysis.⁵⁰ A study by Wilkinson et al.⁵¹ assessed the minimum clinically important difference in both the SF36 and the STS60 following a 12-week renal rehabilitation program. Although the STS60 increased more than the minimal clinically important difference of 4 repetitions in people with CKD not on dialysis, 46 the authors 51 suggest that this minimal clinically important difference may not translate to how participants perceive their functional status when assessed by the SF36, with a greater improvement needed for patients to perceive a positive effect on their health. Another possible explanation is that in the present data set, 14 the control group tended to see a benefit in PCS over time, whereas MCS decreased over

Table 4. Illustrative quotes for theme 2: Strength, fitness and activity for everyday life

Subthemes		Illustrative quotes
Outcomes	Feeling fitter and stronger	"I feel a bit more kind of, like, strong and a bit more balanced." (Female, 58 yr, Stage 2 CKD) "I could feel my body being strengthened week by week by the activities that I was doing on the sessions, and I felt physically stronger." (Male, 49 yr, Stage 3a CKD) "But it is that recovery rate, when you get to the top of the stairs, and you think gosh, I'm not as much out of puff as I
	Physical activity	was 3 months ago." (Male, 76 yr, Stage 3a CKD) "I'm trying to get more exercise. I mean that's one thing good that's come out of it. I am actually doing, physically I'm doing more than I was before I started it. The only unfortunate thing now is of course winter's coming." (Male, 70 yr, Stage 5 CKD) "Before I went on the trial, I was very sedentary. I would take a few walks. I spent a lot of time either deskbound or in
		a car, so I wouldn't really get much in the way of exercise, but attending the trial has really inspired me because not only was I doing the trial and enjoying the sessions, but I also made a very conscious decision to change my lifestyle as well." (Male, 51 yr, Stage 3b CKD) Contrasting quotes
		"No, I don't think so because I think that what I would tend to do is if I was doing, on the days I do the Kidney Beam, I may not go out for a walk or I may do a shorter walk. So, I don't think it made much of a difference to my overall levels of activity." (Female, 65 yr, Stage 2 CKD)
		"Yes, I think so, because that was, obviously I was keeping myself more activity than I was previously and I don't really know if – it wasn't enough for me to notice whether I was become physically more fit or not, but it did feel good to be exercising." (Male, 38 yr, Stage 3a CKD)
	Reduction of fatigue symptoms (experience and perceptions)	"Then now I know that I can do simple exercises without being tired or anything." (Female, 44 yr, Stage 3a CKD) "Before I was just going for dialysis and I was just too tired and sleeping a lot, but at the moment I'm a bit more active and that. I don't get too tired." (Male, 52 yr, Stage 5 CKD)
	Improved function for daily life	"So just silly things like when you're doing the squats and stuff, then you notice it, so I notice it now when I get up and down from the chair, I don't think about it, and then I think back to how I got up and down off a chair in December, not just because obviously I had my stomach cut open, but it was just I had no leg muscles I felt." (Female, 47 yr, Stage 3b CKD)
		"I mean I enjoy feeling a bit stronger in my upper body. When I come to do some work around the house or in the garden." (Male, 65 yr, Stage 3b CKD)
		"Feeling generally fitter and healthier for, yeah, things like when you're walking long distances in life or carrying shopping, just feel like a bit more fit and able to do those things without feeling tired and out of breath." (Female, 29 yr, Stage 1 CKD)
Factors and influences contributing to the outcome	Anyone can do it: accessible exercise	"I think it's very good that you've got people who are sat down as well, you can just choose where you want to be really." (Female, 58 yr, Stage 2 CKD) "I think it's something that no matter what your fitness level is or what your, you know, you think you can do, it's
		something that you can just try." (Male, 49 yr, Stage 3a) "You've got the sitting exercises for people that can't stand up and do it, so it's an inclusive thing for me." (Female,
	Gradual progress	47 yr, Stage 3b CKD) "But it's definitely like built me back up and made me comfortable again and it did get me to a good level again, like to then be able to step into the gym again at a certain level and not just be out of breath in five minutes. So, it definitely was good and got me back up there." (Female, 36 yr, Stage 3b CKD)
		"The phasing of the physical side has been good. They have got slightly harder in time, but I mean I've done twenty- odd sessions now and I can feel the burn. When it started, it was not easy, but it was well suited for my level of fitness which was brilliant and then by the time I got to week ten, it was definitely harder" (Male, 67 yr, Stage 3a CKD)
		"I liked the program as well because it started off quite gently and got more intense as it went on. I thought it was structured really, really well." (Male, 68 yr, Stage 2 CKD).

CKD, chronic kidney disease.

time. Such improvements in PCS may mask any intervention effect and reduce chances of observing statistically significant differences by reducing effect size.

Future DHIs should ensure physical function and confidence in abilities are initially addressed to consequently enhance general physical activity levels and physical function. A similar sequential approach has been suggested in other frail populations.⁵²

The gradual progression of the exercise intensity is emphasized in the UK clinical practice guidelines. ¹ Kidney BEAM allowed participants to individualize their intervention, by choosing to perform the program with other participants, or work through prerecordings individually. This allows for participant choice, and personalization of exercise interventions, which has been reported to be important from the patient perspective. ¹²

An international survey across the Americas, the Middle East, Asia, and the South Pacific of 42, 697 participants revealed a 2-way relationship between mental health and physical conditions.⁵³ Those who had both mental and physical impairments were more likely to have more severe disability.⁵³ Reports from the UK suggest that people living with both mental and physical impairments have poor health outcomes. 54,55 There has been a shift in health care to integrate mental and physical health for people living with longterm physical and mental health issues. 54,55 A recent UK consensus guidelines recommend comprehensive assessment and interventions for both psychological physical rehabilitation for people living with CKD.³ An Australian National Strategic Action Plan for Kidney Disease⁵⁶ recommends optimal care and support includes both physical, mental, and social components. A

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Table 5. Illustrative quotes for theme 3: Discovering new knowledge and skills, to support a more a holistic approach to self-management

Subthemes	Illustrative quotes
Discovering new knowledge and skills for self-management	"The education stuff was quite interesting actually, because there was a couple of bits, I didn't knowI don't really see how you can really improve that much." (Female, 58 yr, Stage 2 CKD) "I didn't really get it until that quite late education session when it became very apparent that my blood pressure was managed by my kidneys. So, it's kind of oh right that penny finally dropped as to why they were checking my kidneys in the first place, and you know why itchy skin and why all sorts of things like that, that I had no idea were part of what the kidney managed" (Male, 67 yr, Stage 3a CKD) "I learned more from the education than I did possibly the – I did get a lot of benefit from the exercise – but the education ones have helped me a lot more with my personal management of my condition" (Male, 49 yr, Stage 3a CKD) "Because it was all just kind of stuff that obviously I didn't know, it was all new information to me". (Male, 39 yr, Stage 3b CKD)
Taking back control	"You know, it's not just about getting fit to do something, I think that you're training people so that they can carry on, you know, looking after themselves as well, which obviously is important" (Female, 58 yr, Stage 2 CKD) "Also, the fact that it's [KB Rx] self-empowering. So much about kidney disease, you're kind of on a treadmill of 'this is how we treat it. This is what we do'. And you can feel quite overwhelmed by everything that's happening around you. Whereas it's like, for me, it was a way of just taking back a bit of control again, which was lovely." (Female, 57 yr, Stage 3b CKD)
Thinking holistically, beyond medications	"So having this kind of platform in every aspect of renal problem or renal disease would help those people who are coming on board, to say you know there are specific kind of exercises, easier on the body, easy on the mind, easy on the brain, emotionally, that could actually break down that anxiety level, that you have before people started this whole process" (Female, 63 yr, Stage 5 CKD) "If you've got a condition, knowing a bit more about it, knowing a bit more about what lifestyle changes can affect it, as opposed to just the interminable amount of pills that we're all diagnosed with, given nowadays, that's got to be a good thing". (Male, 67 yr, Stage 3a CKD) "I think it's [KB Rx] helped positively because it's made me think that there are people out there that want to help and want people to live the best life they can, which you don't always realize that actually the medical team is there for that purpose you know. The side you tend to see when you're having treatment for something long term is just that the day to day, right you've got to take this pill, you've got to take that pill, you've got to do this, that and the other. You can't eat this. You never get that positive "Come on, let's get you well. Let's get you exercising. Let's get you to the best level you possibly can be and live your best life" you know. And it's so nice to see there is something out there to help people do that, to actually achieve that goal' (Female, 52 yr, Stage 3b CKD - when asked about impact if any of KB) "So I think from reading some of the articles on the Beam site as well and also the different chat groups as well, it makes you very much aware that exercise and maintaining a healthy lifestyle really is key to managing a chronic kidney condition as well as the medication, it's not all about the medication, it is about getting that, it's about doing something different. And as well, you know, the mental health benefits from it are paramount, you know, I was very much before I broke the cycle exercise, I was very much not f
Feeling safe and confident to self-manage	"It was as simple as the fact when you've got the get active Kidney Beam classes – they have the instructors standing up and the instructors sitting down and that's why they're saying it doesn't actually matter what level you are and then you think well actually if there's people just who are just sitting down who they can't even – they're doing the exercise anyway – then that gave me a bit more confidence well I can stand up, so of course I can do the exercises." (Female, 47 yr, Stage 3b CKD) "I liked the way that they kept reminding us that we were in charge, it was our body and if it was too strenuous, sit down and if it wasn't strenuous enough, speed up. All of those standard warnings which are probably very good warning were built into the sessions and they just made a lot of sense, and it made you think." (Male, 67 yr, Stage 3a CKD) "I think having attended the workout sessions and doing the downloads and reading and reading that it's OK to do these things and it's OK to feel out of breath, it's OK because you're actually helping yourself now and I think that that's really inspired me a lot." (Male, 51 yr, Stage 3b CKD) "Yeah, I think I discovered that I could safely push myself a little bit more than I thought I could, which was good, I think that some of the things that we were doing kind of made me think well, you know, actually I can do that and it is safe to do that, I'm not going to hurt myself, so that was quite good." (Female, 43 yr, Stage 4 CKD) "They're connecting with you just by, it's how they interact – their tone, the words they use, their, how they motivate you. OK if you can't do this, don't worry about – if you're fired, OK fine. I know this might be, you might be feeling a bit like this. Have a sip of water. OK, if you're feeling like this have a sit down. All these things, it shows that there is care. It's not just about getting someone to do A, B, C, D movements, and any with it and act out. It's not automatin. It's not just about getting someone to do A, B, C, D movements,

CKD, chronic kidney disease. Stages of CKD as per the UK Kidney Association Guidelines.²⁵ All financial disclosures have been submitted by Dr Castle previously.

transplant-specific DHI (Re-fit for life) by the World Transplant Games Federation⁵⁷ also focuses on a combined approach with physical and mental wellbeing at the core of its intervention. This combined physical and mental wellbeing approach was echoed in our Kidney BEAM mixed methods analysis and warrants further exploration in future DHIs.

A key successful component of the Kidney BEAM intervention appears to be the enhanced patient activation, driven by the knowledge and skills the intervention imparted to promote holistic self-management. Patient activation can be defined as an assessment of "a

patient's knowledge, skills, and confidence in managing their own health."⁵⁸ The PAM-13 has been shown to be reliable and valid in people living with CKD, ⁵⁹ with a minimum clinical important difference of 4 arbitrary units. ⁶¹Our quantitative dataset ¹⁴ revealed a mean between group difference of 6.9 arbitrary units on the PAM-13 from intention-to-treat analysis. The participants reported that this was due to the new knowledge and skills facilitated through the Kidney BEAM exercise and education sessions, "taking back control" in their health care, moving beyond the paternal medical model, and feeling safe and confident

get on with it and get out. It's not automatic. It's not automated. It's not fake." (Female, 57 yr, Stage 2 CKD)

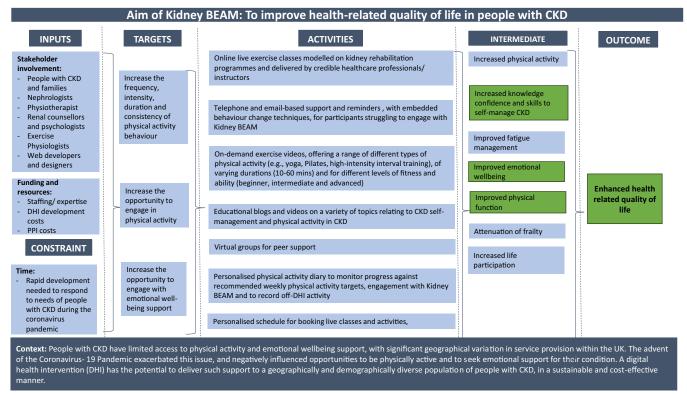


Figure 2. Revised logic model for Kidney BEAM intervention using quantitative data from the intention to treat analysis,14 qualitative interviews from this study, and mixed methods analysis after study. Updated intermediate impacts with green boxes depicting the key elements from integrated analysis explaining the primary findings. The original logic model was presented in the pilot Kidney BEAM manuscript20. CKD, chronic kidney disease.

with exercise. This could reflect the changes seen in the PAM-13 scores, ¹⁴ and improvements in self-efficacy, which can be defined as one's belief in their ability to succeed with a given behavior or task. 60 People living with CKD have suggested the need for the codevelopment of interventions to support selfmanagement, with meaningful input from people with lived experience. 61 Throughout the iterative design, development and evaluation of the Kidney BEAM intervention, input from patient and public involvement stakeholders, 14,16,20,21 and nested qualitative evaluations throughout the pilot phase²⁰ and main trial as discussed in this manuscript, we have ensured that the voice of those with lived experience is central to the intervention delivery. This codesign approach⁶² may well have contributed to the positive experiences reported by our participants and the elements contributing to the effectiveness of the Kidney BEAM

The past 20 years have seen a growth in shared decision making within the field of kidney care. 63-66 Shared decision making is "a collaborative effort between health care professionals, individuals with CKD and their carers or family whereby clinical evidence, expected outcomes and potential side-effects are balanced with individual values and beliefs to provide

the best mutually decided treatment option."65 As a result, shared decision making is a recommended approach in kidney guidelines.⁶⁷ The results from the mixed methods analysis of this current study supports this important shift in practice. Participants report taking back control of their management of CKD. They also reported that Kidney BEAM facilitated their care going beyond medication and the traditional paternal model of medicine. The combined mixed methods results from the qualitative analyses together with the increase in patient activation $(+6.9 \text{ AU})^{14}$ exceeding the minimal clinical important difference (>4 AU)⁶⁸ suggest that the Kidney BEAM intervention empowered participants. Participants were empowered with an increased ability for self-management behavior through new knowledge, skills, and confidence to selfmanage their kidney disease, and overall combined wellbeing.

Strengths and Limitations

A key strength of this study is the mixed methods analyses, allowing further exploration of the clinical effects of the Kidney BEAM intervention observed in a large multicenter trial. ¹⁴ Quantitative and qualitative data sets were collected and analyzed separately and concurrently, before being integrated within a

comprehensive mixed methods analysis. This ensured equal importance of both datasets.34,35 Qualitative reflexivity and rigor were achieved through reflexive diaries as well as collaborative working within both the qualitative team and the wider trial team. In addition, the participant sample included people from across the full CKD spectrum. However, many participants were grade 1 to 3b CKD, with very few interviewed being grade 4 and 5 CKD compared with the quantitative dataset is a limitation to this study. In addition, the baseline eGFR showed moderate impairment (42 ml/ min). The authors anticipate the results of further qualitative substudies within the Kidney BEAM trial, 16 that explore digital inclusion, people receiving hemodialysis therapy, and those who do not have access to a digital Wi-Fi compatible device. As per the main trial, ¹⁴ only those who spoke English were included, which may influence generalizability of these results.

In the UK, current access to kidney-specific rehabilitation health care professionals does not meet national workforce recommendations. Digital innovations such as Kidney BEAM provide a scalable option to deliver a kidney specific DHI to provide improvements in mental, physical, and combined wellbeing. These study findings may assist the design and implementation of other DHIs to support people living with CKD and other long-term conditions to achieve improvements in wellbeing.

As per the protocol paper, 16 the RE-AIM framework (Reach, Effectiveness, Adoption, Implementation and Maintenance)^{29,30} informed the framework analysis across both this and the qualitative work during the pilot phase. For this analysis, we focused on effectiveness; reach and maintenance are addressed in other, or future analyses. Furthermore, we focused on participant experiences and therefore adoption and implementation at the provider level were not evaluated within this manuscript. 16 Only those taking part with the Kidney BEAM intervention were interviewed. However, our pilot study²⁰ included participants in both the waitlist control and intervention group. In addition, this study included UK participants only. Therefore, the results may not be directly applicable to other health care settings. Future studies could explore the health care professional perspective, and participants from other countries and health care settings to further inform implementation.

CONCLUSION

Integrated analyses of quantitative and qualitative datasets explored elements of the Kidney BEAM complex DHI that contributed to the clinically meaningful and statistically significant effects seen in the main

Kidney BEAM Trial (mental HRQoL, patient activation, and physical function measured by the STS60).

Interview participants reported mental, physical, and enhanced self-management benefits realized through use of the Kidney BEAM intervention. These were driven by the ability for people of all functional levels to take part in the program, the gradual progression of exercise, the shared lived experiences with other participants, self-monitoring of the program, the sense of achievement, taking back control of their health, moving beyond medications, and feeling safe and confident to exercise. The results from these mixed methods analyses will allow researchers and practitioners to maximize effectiveness of DHIs and enhance healthy behaviors in people living with CKD.

DISCLOSURE

King's College Hospital NHS Trust and SG were involved in the conception and development of the Kidney BEAM DHI. All the other authors declared no conflicting interests.

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DATA AVAILABILITY STATEMENT

Quantitative data from the main trial, ¹⁴ including deidentified participant data, will be made available on reasonable request, and following trial steering committee approval, but contacting the senior author (Sharlene. greenwood@nhs.net). The study protocol, statistical analysis plan, and other study forms for the main trial were previously published. ²⁰ The ethical review board for the Kidney BEAM trial was granted from the Bromley National Health Service (NHS) Research Ethics Committee (REC) and the Health Research Authority (HRA) (reference 21/L0/0243). ¹⁴ The qualitative data presented in this paper, the transcript data are not publicly available due to privacy or ethical restrictions. Consent was not given for the full publication of transcripts. However, further detail on the

qualitative data that support findings of this study are available on request from the corresponding author (ellen. castle@curtin.edu.au). Mixed methods data is presented throughout this manuscript and associated supplementary materials.

AUTHOR CONTRIBUTIONS

The authorship followed ICMJE guidelines. EMC, HMLY, REB, JB, CW, JM, and SAG were responsible for the inception and design of the project. All the authors made substantial contributions to the acquisition; analysis or interpretation of data; and drafting the manuscript text, tables, figures, and supplementary material. All the authors reviewed and approved the final version of the manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

Figure S1. Topic guide for qualitative interviews.

Figure S2. Figure demonstrating the kidney BEAM project including design, development, and evaluation.

Table S1. COREQ checklist.

Table S2. Details of the qualitative team.

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