RESEARCH

Utilizing technology for diet and exercise change in complex chronic conditions across diverse environments (U-DECIDE): feasibility randomised controlled trial

Riley C. C. Brown[1,2], Shelley E. Keating[1,2], Dev K. Jegatheesan[3,4], Hannah L. Mayr[4,5,6], Amandine Barnett[7,8], Marguerite M. Conley[5], Lindsey Webb[5], Jaimon T. Kelly[7,8], Centaine L. Snoswell[7,8], Heidi M. Staudacher[9], Graeme A. Macdonald[4,10], Nicola W. Burton[11,12,13], Jeff S. Coombes[1,2], Katrina L. Campbell[8,12,14], Nicole M. Isbel[3,4] and Ingrid J. Hickman[4,5*]

Abstract

Background Diet and exercise are important components of treatment for complex chronic conditions, however access to allied health support is limited. When available, support is often siloed and fragmented. Digital health incorporating patient choice may help to align health care services with preferences and goals. This study evaluated the implementation of a ubiquitously accessible patient-centred digital health diet and exercise service.

Methods U-DECIDE was a single-centre, 26-week randomised controlled trial set in kidney and liver disease clinics in a tertiary hospital in Brisbane, Australia. Participants were adults with a complex chronic condition referred for die-tetic consultation with at least one feature of the metabolic syndrome. All participants received a dietary consultation, an activity monitor and usual care. Intervention participants were offered one text message per week and access to additional digital health options (increased text message frequency, nutrition app, exercise app, group-based diet and/or exercise video consultations). The primary outcome of feasibility was determined by safety (study-related seri-ous adverse events: SRSAEs), recruitment (≥ 50% eligible patients), retention (≥ 70%), exposure uptake (≥ 75% of inter-vention group had greater access to health professional contact than comparator) and video consultation adherence (≥ 80% attendance). Secondary outcomes included process evaluation metrics and clinical outcomes.

Results Of 67 participants (intervention *n* = 33, comparator *n* = 34), 37 (55%) were men, median (IQR) age was 51 (41–58) years. The most chosen digital health options were the nutrition app (*n* = 29, 88%) and exercise video con-sultations (*n* = 26, 79%). Only one participant chose no additional digital health options. The intervention group had no SRSAEs. The study exceeded targets for recruitment (52%), retention (81%) and exposure uptake (94%). Video consultation adherence was 42%. Engagement across digital health options was inconsistent.

Conclusions Digital health options incorporating patient choice were feasible and can be offered to people with complex chronic disease as a service model option.

*Correspondence:
Ingrid J. Hickman
i.hickman@uq.edu.au
Full list of author information is available at the end of the article

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 2 of 18

Background

Complex chronic conditions such as liver and kidney disease are prevalent and associated with increased cardiometabolic risk. The treatment of associated cardiometabolic dysfunction represents a substantial burden on the health system [1]. Improving diet quality and increasing physical activity are critical components of treatment [2]. Due to the complexity of multimorbid patient cohorts, management is often through specialist teams located at hospital clinics, not in primary care settings [3, 4]. Despite broad similarities in patient diet and exercise needs across different chronic conditions, these services are typically aligned to and delivered in a siloed specialist setting [3, 5]. Tertiary outpatient services often have insufficient resources to deliver health practitioner contact at the frequency and intensity required for sustained behaviour change [6–8]. Where services do exist in our local context, they are often fragmented and require appointments with multiple healthcare professionals which are typically restricted to one-on-one, in-person consultations. This approach is costly and uncoordinated, places a significant burden on the patient and does not meet their expressed needs [6–9]. A digital health approach through a unified complex chronic disease model of care for exercise and diet services targeting improved metabolic health could create efficiencies and improved access in these settings.

Recent advances in digital health bring opportunities to better assist diet and exercise interventions [10]. Although much of the evidence is limited to single health conditions and research settings, it provides a compelling value proposition offering significant efficiency gains over the traditional in-person approach [11–13]. There remains a need to evaluate interventions in people with multimorbid complex conditions in a real-world setting. Digital health interventions can increase flexibility in access [14]. Incorporating patient choice of intervention may lead to improved engagement and clinical effectiveness [15, 16].

The objective of this study was to evaluate the implementation of digital health diet and exercise services for people with complex chronic conditions being managed in a tertiary hospital outpatient setting. The primary aim was to determine the feasibility of a ubiquitous chronic condition, diet and exercise digital metabolic health service, incorporating patient choice. This was determined by safety, recruitment rate, retention, exposure uptake and video consultation adherence. The secondary aims were to evaluate patient choices and engagement with digital health options, as well as clinical outcomes and economic impact from a health services perspective.

Methods

Study design and participants

A detailed trial protocol has been previously described [17]. This was a single-centre, 26-week, parallel randomised controlled trial with a 1:1 allocation ratio conducted in a tertiary public hospital in Brisbane, Australia. The study was run between December 2020 and June 2022 (U-DECIDE study; Australia and New Zealand Trials Register: ACTRN12620001282976). The study was approved by the Metro South Human Research Ethics Committee (HREC/2019/QMS/58285) and The University of Queensland Human Research Ethics Committee (2020000127) and conformed with the Declaration of Helsinki. This study is reported in line with the CONSORT extension to pilot and feasibility trials [18] and Template for Intervention Description and Replication (TIDieR) [19] guidelines.

Adults living with kidney or liver disease who were at increased cardiometabolic risk based on the presence of one or more components of the metabolic syndrome and receiving specialist care at the Princess Alexandra Hospital in Brisbane, Australia were the targeted participants. Eligibility criteria included: i) under the outpatient care of at least one of the following specialist hospital clinics: kidney or liver transplant, chronic kidney disease (CKD), haemodialysis, peritoneal dialysis or hepatology; ii) having (or be undergoing treatment for) at least one of the features of the metabolic syndrome, as defined by the harmonised criteria [20]; iii) approved for participation by their treating medical specialist; iv) screened as physically capable to participate; and v) having access to a mobile device or computer hardware with internet access and webcam capability. Exclusion criteria were: i) non-English speaking or unable to read and write in English; ii) documented malnutrition; iii) < 18 or > 80 years of age; iv) currently pregnant or breastfeeding; and v) life expectancy < 6 months.

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 3 of 18

Randomisation and blinding

Potentially eligible patients were sourced by screening medical specialist referrals to the dietetics department and invited to participate by the research project officer (LW). Participant information and consent forms were provided in advance of baseline assessment, and written informed consent was obtained at in-person attendance at the baseline appointment. Participants completed a medical history and exercise safety questionnaire to screen for any conditions that may have impacted safety. Before baseline appointments, any participant who had a potential contraindication to exercise training was referred to their treating specialist for a decision regarding inclusion/exclusion. Participants underwent baseline testing before 1:1 randomisation to either the intervention or comparator groups (see Fig. 1). Computer-generated randomisation was performed by the research project officer using the REDCap research management system, with groups being stratified by referral source: i) CKD clinic, ii) hepatology clinic, iii) liver or kidney posttransplant clinic. Assessors who completed end-of-program clinical assessments were blinded to group allocations.

Procedures

All participants

All participants received usual medical and specialist care and were offered an initial individualised dietary consultation with a dietitian, and a wearable activity monitor (Fitbit Inspire HR™; Fitbit, Inc, San Francisco USA) for 24-h wear, for continual monitoring of physical activity through the study period.

Intervention group

The intervention group were offered access to a suite of digital health options with a mix of minimum required and additional patient-selected components [17]. All intervention participants received semi-personalised and unidirectional lifestyle-related text messages. At baseline, participants were able to choose the desired frequency of text messages: once, twice or three times per week, and the option of engaging with any number of different digital health options, which was an indication of intended engagement with the digital health strategies. Participants could choose to have access to a nutrition app (Sophus Health Pty Ltd, Brisbane, Australia; accessible via smart device application and website; for more information refer to supplementary material 3), an exercise app (Physitrack Ltd, London, UK; accessible via smart device application and website), video consultations with
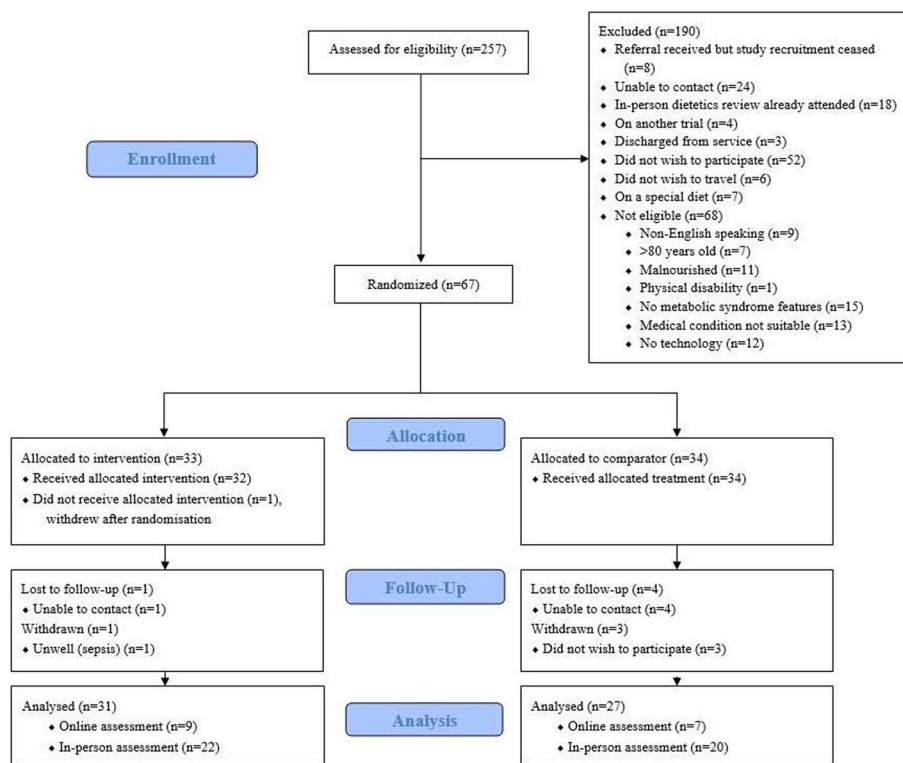

Fig. 1 Participant flow

Brown *et al. BMC Health Services Research* (2024) 24:935

Page 4 of 18

an accredited practicing dietitian (45min group dietitian reviews offered monthly) and/or video consultations with an accredited exercise physiologist (60 min group exercise sessions offered weekly with maximum six participants per group). Dietitian video consultations were intended to cover heart healthy nutrition topics, and were participant-led, with prompts from pre-set monthly topics if needed. Exercise physiology video consultations included supervised aerobic and resistance exercise. Further details for the intervention have been previously described [17].

Comparator group

Participants in the comparator group were offered individualised dietitian review as per standard care (either face to face or telephone) at a frequency deemed clinically appropriate for the individual. Topics discussed depended on individual clinical interactions in each session. There was no routine access to exercise specialists in the comparator group.

Outcomes

The primary outcome was feasibility. Secondary outcomes included process evaluation metrics (participant choices, engagement with nutrition app and wearable activity monitor, dietitian review topics), adverse events of special interest, costs and clinical outcomes. Outcome measures are as previously described in detail elsewhere [17].

Primary outcome

The determination for feasibility was that the intervention was safe and at least three of the four *a priori* criteria (recruitment, retention, exposure uptake, video consultation adherence) were fulfilled. Safety was assessed by comparing if the number of study-related serious adverse events (SRSAEs) in the intervention and comparator groups was similar (supplementary material 1). All serious adverse events (SAEs) were reviewed by an independent medical officer and potential relationship to the study procedures classified as none, unlikely, possible or probable. An event was considered study-related if coded as possible or probable. The additional four *a priori* feasibility criteria were: i) ≥ 50% of all referred eligible patients were recruited (recruitment), ii) ≥ 70% of participants underwent an end-of-program assessment (retention), iii) ≥ 75% of intervention participants had a higher frequency of specialist outpatient dietetic and exercise specialist contact than the comparators (exposure uptake), and iv) dietetic and exercise video consultations had an attendance rate of ≥ 80% of the total scheduled contacts (video consultation adherence) [17].

Secondary outcomes
Process evaluation metrics

Participant choices Patient-led choice of digital health options (text message frequency, nutrition app, exercise app, exercise and/or diet video consultations) was collected at baseline assessments. In addition, education topics discussed in dietitian review sessions (both study groups) was extracted from clinician session notes with topics broadly classified into food-based education, dietary pattern education, nutrient and/or disease specific education and behaviour strategies (supplementary material 2 and Figure S2.1).

Engagement with nutrition app and activity monitor Participants were able to access the nutrition app as they desired. The platform provided quarterly key metrics including: number of active users, date and frequency of engagement per session, the type of device used, and the pages accessed (supplementary material 3).

At study end, engagement with wearable activity monitor was determined from device wear-time compliance, calculated across the entire study length.

Adverse events of special interest

Adverse events (AEs) of special interest including musculoskeletal injuries were also independently reviewed throughout the study (supplementary material 1). All participants were asked at the end of study if they had experienced any AEs during the study that had not yet been reported.

Clinical outcomes

Clinical outcome data were collected at baseline and end-of-program assessments.

Metabolic syndrome severity score The Metabolic Syndrome Severity Score (MetSSS; calculations provided in supplementary material 4) [21] is a continuous risk assessment score for quantifying the metabolic syndrome.

Physical activity Self-reported physical activity was measured using The International Physical Activity Questionnaire Short Form (IPAQ-SF) [22]. The IPAQ-SF classification system is provided in supplementary material 5. Objectively assessed moderate-to-vigorous intensity physical activity (MVPA) was measured with a wearable activity monitor (Fitbit Inspire HR™). Participants were asked to synchronise their wearable activity monitor to the Fitbit® app daily to assess MVPA and wear-time compliance. Wear-time compliance was

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 5 of 18

determined via days per week the device was worn. Study investigators assessed physical activity data on a weekly basis for implausible data (i.e. whole day MVPA totals not commensurate with tracked exercise sessions; days with < 1000 steps). Implausible records of physical activity were manually re-assessed to confirm if any tracking errors had taken place. This was completed by extracting MVPA data from automatically recorded exercise sessions, not full-day totals.

Exercise capacity   The 6-Minute Walk Test (6MWT) was used to assess exercise capacity [23].

Neuromuscular fitness   The five times sit to stand (5xSTS) [23] was used to assess functional lower limb neuromuscular strength and endurance. Neuromuscular strength was assessed using the hand grip strength test (HGS) [13].

Muscular pain   Participants completed the Modified Nordic Musculoskeletal Questionnaire (MNMQ) [24] to quantify musculoskeletal pain.

Health-related quality of life   The EQ-5D five level scale (EQ-5D-5L) was used to assess health-related quality of life [25].

Fatigue   Fatigue was assessed using the Functional Assessment of Chronic Illness Therapy Scale (FACIT) [26]. Potential FACIT scores range from 0 to 52, with a lower score indicating more severe fatigue.

Sleep quality and quantity   The Pittsburgh Sleep Quality Index (PSQI) was used to quantify sleep quality and quantity [27].

Dietary quality   Dietary quality assessment included a 3-day self-administered digital food record in mobile app Research Food Diary (Xyris Software Pty Ltd, Australia) on the participant's personal device which was analysed using FoodWorks 10 Professional (Xyris Software Pty Ltd, Australia).

Additional clinical parameters   Resting heart rate, body mass index (BMI) and blood composition were evaluated at assessment sessions. Any change in medication use was recorded at study completion and categorised as newly initiated, increased dose, decreased dose or ceased.

Economic analysis – health services perspective

Service costs were estimated from the perspective of the hospital for an average patient using the resource method, where resource volumes and costs were gathered from trial data and the usual care offered by the health service. Human resources included dietitians, exercise physiologists and administration support for consultations. Other resources included the Fitbit Inspire HR™ and software costs for the Sophus and Physitrack apps. Australia operates a publicly funded hospital and health service, freely available to citizens. The model of government funding reimbursement to a Queensland hospital is calculated based on a price per activity delivered [28]. Financial suitability was assessed by comparing economic gain from intervention and usual care groups based on local funding models established for reimbursement for outpatient activity, giving a final assessment of health service sustainability within current funding models.

Statistical analysis

As this was a feasibility study, sample size calculation was not performed for the primary outcome which compared participants against *a priori* feasibility criteria [29]. A sample size calculation was performed using the MetSSS as a secondary outcome. Our final sample size is similar to other feasibility trials using digital health exercise or diet interventions in chronic disease groups [30, 31]. MetSSS was chosen as a reflection of the metabolic complexity of this cohort. Assuming a correlation of 0.5 between baseline and 26-week MetSSS and an effect size of 0.42 (representing a change of 0.8 in the intervention group and no change in the comparator group, with a pooled SD of 1.9), 67 participants per group would be required to achieve 80% power to detect a significant difference at the 5% level (2-sided) using an analysis of covariance (ANCOVA) with the baseline value as the covariate. Allowing for 20% dropout, the sample size required for this secondary outcome was determined to be 168 (84 per arm).

Secondary outcome data were analysed using Statistical Package for the Social Sciences (SPSS version 28.0; IBM Corp., Armonk, NY, USA). Secondary outcome data were tested for normality using the Shapiro–Wilk test and visual inspections of histograms and residuals Q-Q plots. All secondary outcome data are presented as mean values ± standard deviation (SD) if normally distributed and median [interquartile range] if not, unless otherwise stated. Assumptions testing for ANCOVA were verified. When data violated assumptions testing, Quade Nonparametric ANCOVA was used. Effect sizes are reported as η2 (eta-squared), which measures the proportion of variance associated with each main effect and the interaction effect in an ANOVA model and is calculated as the between-group sum of squares/total sum of squares. These effects were interpreted as negligible (0.00); small

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 6 of 18

(0.01); small-to-moderate (0.01–0.09); medium-to-large (0.10–0.25) and large (>0.25) [32]. Chi-squared and Mann–Whitney U tests were used to assess demographic differences in participants who did/did not have diet record data. There was no imputation for missing data as this was deemed inappropriate based on the sample size. The analyses were two-tailed with significance set as $p < 0.05$.

Results

Participant flow is described in Fig. 1. There were significant COVID-19 related disruptions affecting recruitment, including outpatient clinic closures and/or restrictions on in-person attendance. Due to these circumstances, the trial was ceased prior to reaching the recruitment target. Investigators made decisions to cease whilst blinded to primary feasibility criteria results. It was widely considered that the sample achieved would have been greater if not for covid-related disruptions to the healthcare system. Participants were recruited from December 2020 to November 2021. Sixty-seven participants were randomised into either the intervention ($n=33$) or comparator group ($n=34$).

Participant summary characteristics at baseline are shown in Table 1. Twenty-eight participants were recruited from kidney outpatient clinics (median eGFR=17.5 mL/min^2 (IQR=9.5 to 60.8 mL/min^2)). Median FACIT score aligned with profound fatigue and was similar to that seen in other kidney and liver disease cohorts [33, 34]. Mean MetSSS represented substantial metabolic disturbance [21], and 60% ($n=40$) had low physical activity levels. EQ-5D-5L median index values were lower than similar cohorts [35], representing decreased health-related quality of life. Polypharmacy was evident with an average of 7.9±4.7 medications administered daily. Muscle pain in the last week was reported by 73% of participants.

The feasibility of the digital health approach was confirmed (Table 2). This included criteria of safety (no SRSAEs in either group); recruitment (51.9%); participant retention (80.6%) and exposure uptake (94.0%). Video consultation adherence targets were not met, with an attendance rate of 42.2% for intervention participants (supplementary material 6 Table S6.1). Differences in health professional exposure between the intervention and comparator groups are shown in Fig. 2.

Details on safety and adverse events of special interest are provided in Table 3. There were 44 non-study related SAEs ($n=21$ in the intervention, $n=23$ in the comparator). All but one SAE were hospitalisations with $n=20$ planned and $n=23$ unplanned admissions. There were 31 AEs ($n=21$ in the intervention, $n=10$ in the comparator group). There were five study-related AEs ($n=4$ musculoskeletal, $n=1$ chest pain), all in the intervention group.

Digital health choices for participants in the intervention group are displayed in Table 4. Nineteen participants (58%) selected three text messages per week, six chose two (18%) and seven chose one (21%). The most frequently self-selected digital health options at baseline were the nutrition app ($n=29$, 88%) and group video consultation exercise physiology sessions ($n=26$, 79%). Twenty-five participants in the intervention group (76%) selected at baseline to have video consultation dietitian review sessions, although five of these participants did not attend any reviews (supplementary material 6 Figure S6.1). The median attendance for the remaining 20 participants was two of five (40%) available video consultations (range 1 to 4). Of the 34 participants in the comparator group, 17 (50%) did not attend any dietetic reviews while the median attendance for the remaining 17 participants was one review session (range 1 to 4). Of the 26 participants in the intervention group who selected at baseline to access video consultation exercise sessions, two (7.7%) did not attend any sessions. The median attendance for the remaining 24 participants was 12 sessions (46%; range 1 to 24). Usual clinic care did not include hospital-based exercise specialist services, so this was not available to the comparator group.

Thirty participants (91%) in the intervention group chose at baseline to engage with the nutrition app. However, only 18 of these (60%) engaged with the app, nine (30%) did not engage and for three (10%) engagement could not be determined (missing analytic data). Fourteen participants engaged with the app via their mobile phone (78%), two via their personal computer (11%) and two used a combination of the two (11%) for a median of 2 occasions (IQR: 1–4.5) in the first month and then less often subsequently (Fig. 3). Of those who did engage with the app, all features were accessed at least once by 13% ($n=4$) (Frequency of fact sheet access shown in supplementary material 7 Figure S7.1). Of the 183 days when participants had access to the nutrition app, engagement occurred for a median of 39.5 days (IQR 8.3—129.8), with a median time between each engagement session of 10.2 days (IQR 4.9—41).

Digital food records were completed for both baseline and end-of-program assessments by 44 (66%) participants ($n=24$ intervention, $n=20$ comparator group). Participants wore the wearable activity monitor for an average of 79±28% of the duration of the study (72±28% intervention group and 85±26% comparator group).

Due to the impacts of COVID on study recruitment and the early cessation of recruitment, the study was underpowered for most secondary clinical outcomes. Closure or restricted physical access to outpatient clinics

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 7 of 18

Table 1 Baseline participant characteristics

	Intervention ($n = 33$)	Comparator ($n = 34$)	Total ($n = 67$)
Demographics			
Sex (M/F), n	17/16	20/14	37/30
Age category (years), n (%)			
18 to 25	2 (6)	1 (3)	3 (4)
26 to 40	6 (18)	8 (24)	14 (21)
41 to 50	5 (15)	9 (26)	14 (21)
51 to 60	10 (30)	10 (29)	20 (30)
61 to 70	9 (27)	6 (18)	15 (22)
> 70	1 (3)	0 (0)	1 (1)
Ethnicity[#], n (%)			
European Australian	27 (82)	25 (74)	52 (78)
Indigenous	1 (3)	2 (6)	3 (4)
Asian	3 (9)	1 (3)	4 (6)
Other	4 (12)	8 (24)	12 (18)
Disease stratification as per referral source, n (%)			
Chronic kidney disease	13 (39)	15 (44)	28 (42)
Liver disease	4 (12)	3 (9)	7 (10)
Kidney/liver transplant	16 (49)	16 (47)	32 (48)
Education level, n (%)			
< Grade 10	4 (12)	3 (9)	7 (10)
Grade 10	5 (15)	3 (9)	8 (12)
Grade 12	5 (15)	4 (12)	9 (13)
TAFE/College	12 (36)	13 (38)	25 (37)
University	7 (21)	11 (32)	18 (27)
Employment, n (%)			
Full-time	9 (27)	13 (38)	22 (33)
Part-time	5 (15)	5 (14)	10 (15)
Unemployed	8 (24)	7 (20)	15 (22)
Self-employed	5 (15)	1 (3)	6 (9)
Student	0 (0)	2 (6)	2 (3)
Retired	6 (18)	6 (18)	12 (18)
Co-morbidities, n (%)			
Hypertension	23 (70)	21 (62)	44 (66)
Obesity	22 (70)	20 (59)	42 (63)
Diabetes	8 (24)	9 (26)	17 (25)
Dyslipidaemia	10 (30)	14 (41)	24 (36)
Polypharmacy, total number of medications	8.8 ± 4.9	6.9 ± 4.3	7.9 ± 4.7
Anthropometry			
Waist circumference (cm)	109.5 ± 14.6	114.3 ± 18.3	112.0 ± 16.6
Body mass index (kg/m^2)[^]	33.2 [30.1 to 36.6]	33.4 [28.9 to 36.9]	33.3 [29.4 to 36.9]
Blood pressure			
Systolic blood pressure (mmHg)[^]	130 [121 to 139]	131 [124 to 138]	130 [123 to 139]
Diastolic blood pressure (mmHg)[^]	81 [77 to 85]	85 [78 to 88]	84 [78 to 86]
Fasting blood measures			
Glucose (mmol/L)[^a]	5.7 [5.1 to 7.2]	5.7 [5.3 to 7.0]	5.7 [5.1 to 7.1]
Triglycerides (mmol/L)[^b]	1.8 [1.4 to 2.5]	1.6 [1.1 to 2.4]	1.7 [1.3 to 2.4]
High-density lipoprotein cholesterol (mmol/L)[^c]	1.1 [1.0 to 1.3]	1.0 [0.9 to 1.3]	1.1 [0.9 to 1.3]
Metabolic syndrome severity			
MetSSS[d]	3.73 ± 1.64	3.94 ± 1.98	3.83 ± 1.80

Table 1 (continued)

	Intervention (*n* = 33)	Comparator (*n* = 34)	Total (*n* = 67)
Exercise capacity			
6-minute walk test (m)[e]	459.3 ± 95.7	440.3 ± 93.3	451.0 ± 94.4
Neuromuscular fitness			
Five times sit to stand (s)[^a]	14.4 [12.6 to 18.1]	16.3 [14.8 to 19.9]	15.9 [13.4 to 18.4]
Hand grip strength (dominant) (kg)[^e]	29.6 [24.6 to 44.7]	32.7 [26.6 to 38.5]	30.9 [24.8 to 40.4]
Physical activity			
International physical activity questionnaire classification, n (%)			
Low	18 (55)	22 (65)	40 (60)
Moderate	13 (39)	8 (24)	21 (31)
High	2 (6)	4 (12)	6 (9)
Muscle pain			
Modified Nordic musculoskeletal questionnaire (MNMQ)			
Trouble[a] in at least one area in the last week, n (%)	25 (76)	24 (71)	49 (73)
Trouble[a] in three or more areas in the last week, n (%)	14 (42)	17 (50)	31 (46)
Pain intensity (sum of 9 areas[b])[^f]	10 [5 to 22]	13 [5 to 25]	12 [5 to 23]
Fatigue			
Functional assessment of chronic illness scale (FACIT)[^]	35 [24 to 43]	39 [25 to 45]	35 [25 to 44]
Sleep quantity and quality			
Pittsburgh sleep quality index (PSQI)	9.5 (4.4)	8.4 (4.0)	8.9 (4.2)
Quality of life			
European quality of life five dimension five levels scale (EQ-5D-5L)			
Index value, n[^]	0.783 [0.633 to 0.924]	0.739 [0.526 to 0.859]	0.759 [0.559 to 0.898]
VAS score, n[^e]	70 [45 to 80]	62 [46 to 79]	66 [45 to 80]

Data presented in mean ± SD unless otherwise stated

Abbreviations: n Number, *M/F* Male/female, *TAFE* Vocational college, *MetSSS* Metabolic syndrome severity score, *VAS* Visual analogue scale

[#] Can choose more than one option. [^]Median [IQR]. [a]*n* = 65. [b]*n* = 55. [c]*n* = 54. [d]*n* = 53. [e]*n* = 66. [f]Maximum sum of 9 areas = 90

Table 2 Primary outcome results

Feasibility outcome	Success criteria	Result	Feasibility success
Safety	Number of study-related SAEs similar between intervention and control groups	0 SAEs related to the study intervention	**Yes**
Recruitment rate	≥ 50% of all referred eligible patients recruited	51.9% (67 of 129)	**Yes**
Retention rate	≥ 70% of participants assessed at baseline undergo an end-of-program assessment	80.6% (54 of 67)	**Yes**
Exposure uptake	≥ 75% of intervention participants have a higher frequency of specialist outpatient dietetic and exercise specialist contact than the controls	94.0% (32 of 34)	**Yes**
Telehealth adherence	Videoconferencing dietetic and exercise sessions have an attendance rate of ≥ 80% of the total scheduled contacts	42.2% (338 of 801)	**No**
Feasibility success confirmed (safety + three criteria)			

Abbreviations: SAEs Serious adverse events

saw large variation in participant numbers for outcome measures that require specialised equipment and/or in-person administration such as hand grip strength, exercise capacity testing and or composite score measures (e.g. MetSSS). Rates of missing data for these measures are shown in supplementary material 8 Table S8.1.

Clinical outcomes are presented in Table 5. Dietary quality is presented in Table 6 and supplementary material 9 Table S9.1. Acknowledging recruitment targets were not met, there were no significant between group differences detected for change in any clinical variable adjusted for baseline and no change in the
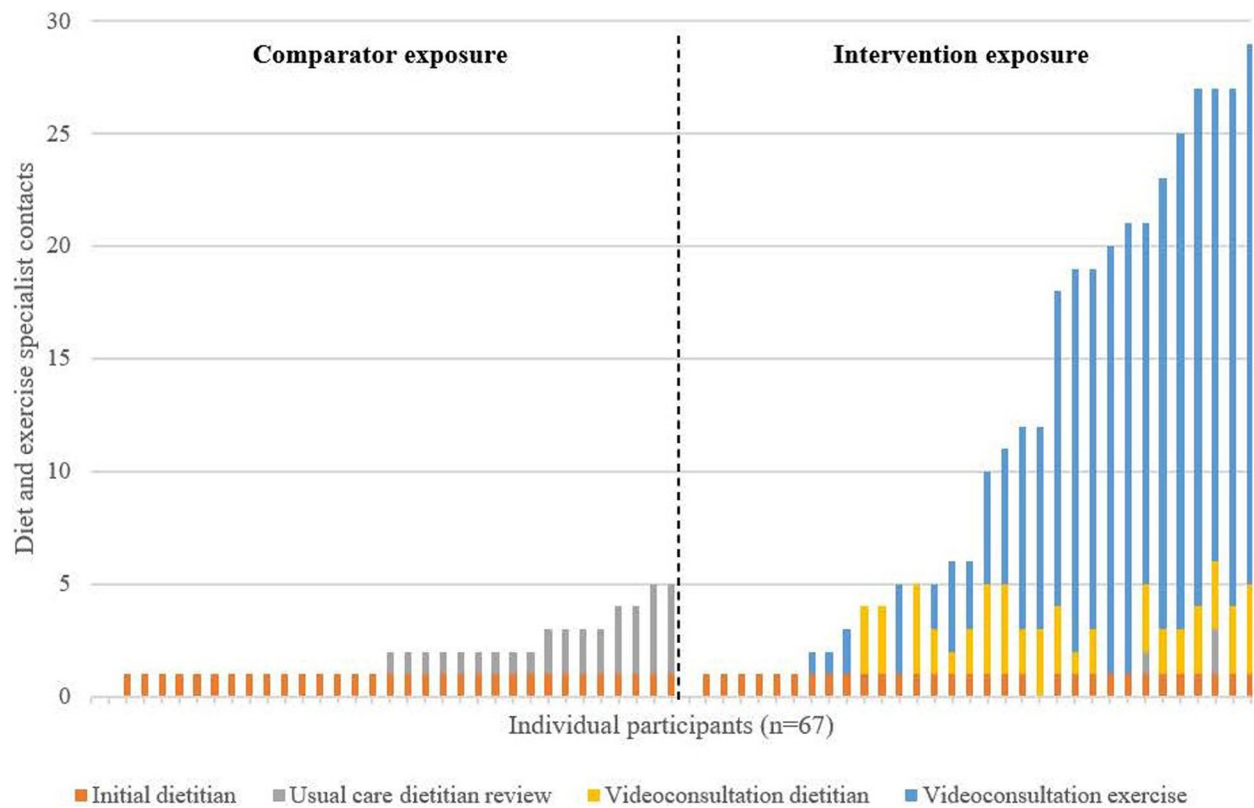
Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 9 of 18

Fig. 2 Exposure to health professional contacts through video-based or in-person diet and exercise sessions in the intervention and comparator groups. Each bar represents an individual participant

number or type of medications taken by participants in each group.

At baseline, self-reported physical activity was most commonly categorised as low (60%) (Table 1). On average, each week $27 \pm 31\%$ of participants in the intervention group and $23 \pm 30\%$ in the comparator group attained 150 min per week of MVPA.

The average cost (min–max range) per patient for the intervention was $935.34 ($758.15—$3,139.60), while usual care was $183.49 ($126.88—$461.71) (supplementary material 10 Table S10.1). These costs were offset through local remuneration schemes to reimburse the hospital for outpatient consultations, creating an economic gain of $833.66 (-$431.15—$1,675.40) for the intervention group and $89.01 ($36.12—$79.71) for usual care, with a return on investment of $1.89 ($0.43—$1.53) compared to $1.49 ($1.28—$0.83). This gain was the result of state-based hospital activity-based funding that could be claimed for clinical activities within each model, which offset the costs of each service delivery [28]. The intervention group average costs, net-benefit and ROI were very sensitive to changes in variables related to technology costs (48% of the total cost), dietitian costs (16% of the total cost), and remuneration derived from

the exercise physiologist group consultations (77% of total remuneration).

Discussion

This study evaluated digital health diet and exercise services for people with complex chronic conditions being managed in a tertiary hospital outpatient setting. The main finding was that digital health options to access specialist diet and exercise professionals and resources were feasible in terms of safety, recruitment, retention and exposure uptake. Video consultation adherence was higher than review appointment attendance in the comparator group but did not meet the *a priori* criteria target of 80% attendance.

Participants in this study generally presented with multimorbidity, significant polypharmacy, profound fatigue and musculoskeletal impairment at baseline. The multiple hospital admissions during the study demonstrates the clinical complexity of this patient group. They remain vulnerable to and dependent on the healthcare system. Complex patients of this nature are typically excluded from lifestyle intervention trials and are therefore under-represented in the feasibility testing of digital health innovations. Digital diet and exercise services,

Table 3 Number and type of serious adverse events and adverse events of special interest

	Comparator n = 34	Intervention n = 33	Total Group n = 67
Serious adverse events, n			
Total	23	21	44
Hospitalisation (planned)	8	12	20
Hospitalisation (unplanned)	14	9	23
Other	1	0	1
Study-related	0	0	0
Adverse events of special interest, n			
Total	10	21	31
Study-related	0	5	5
Number of participants that experienced at least one adverse event of special interest, n (% of group)	9 (26)	15 (45)	24 (36)
Hypoglycaemia, n	0	0	0
Falls, n			
Total	2	2	4
Grade 1 Minor	1	1	2
Grade 2 Symptomatic	1	1	2
Musculoskeletal injury, n			
Total	5	15	20
Mild	3	5	8
Moderate	2	9	11
Severe	0	1	1
Hyperkalaemia, n	0	0	0
Low Blood Pressure, n	0	1—mild	1 – mild
Chest pain, n			
Total	0	2	2
Mild	0	1	1
Moderate	0	1	1
Covid infection during study, n	3	1	4

Abbreviations: n Number

ubiquitously accessible across specialist services, identified no safety concerns and were deemed a viable form of intervention delivery.

Patient choice was a novel aspect of this trial. Offering participant choice in intervention dose or exposure

Table 4 Digital health choices made at baseline by participants in the intervention group (Participant choices)

Digital health option	n (%)
Text message (1 × weekly)	7 (21)
Text messages (2 × weekly)	6 (18)
Text messages (3 × weekly)	19 (58)
Nutrition app	29 (88)
Group video consultation dietetics (1 × monthly)	25 (76)
Group video consultation exercise physiology (1 × weekly) with exercise app	26 (79)
Exercise app only (asynchronous)	3 (9)

Abbreviations: n Number

is an emerging innovative strategy in RCT designs [15] and offering patient choice in telehealth service delivery options is not widely adopted across the health service in our local context [36]. The range of technologies chosen by participants signalled an intention to engage with digital health strategies and indicates no single defined model of care would be suitable for all. Previous trials investigating the effect of patient choice on health outcomes report positive results, such as improvements in intervention adherence and outcomes of psychosocial/physical functioning [15, 16]. In the current study, the degree of engagement with the options chosen did not consistently align with the intentions of participants when first offered digital health. Given that intentions may be subject to change over time [37], future interventions employing a patient choice model may benefit from 'check-in' points where participants have an opportunity to reassess and modify their selections.
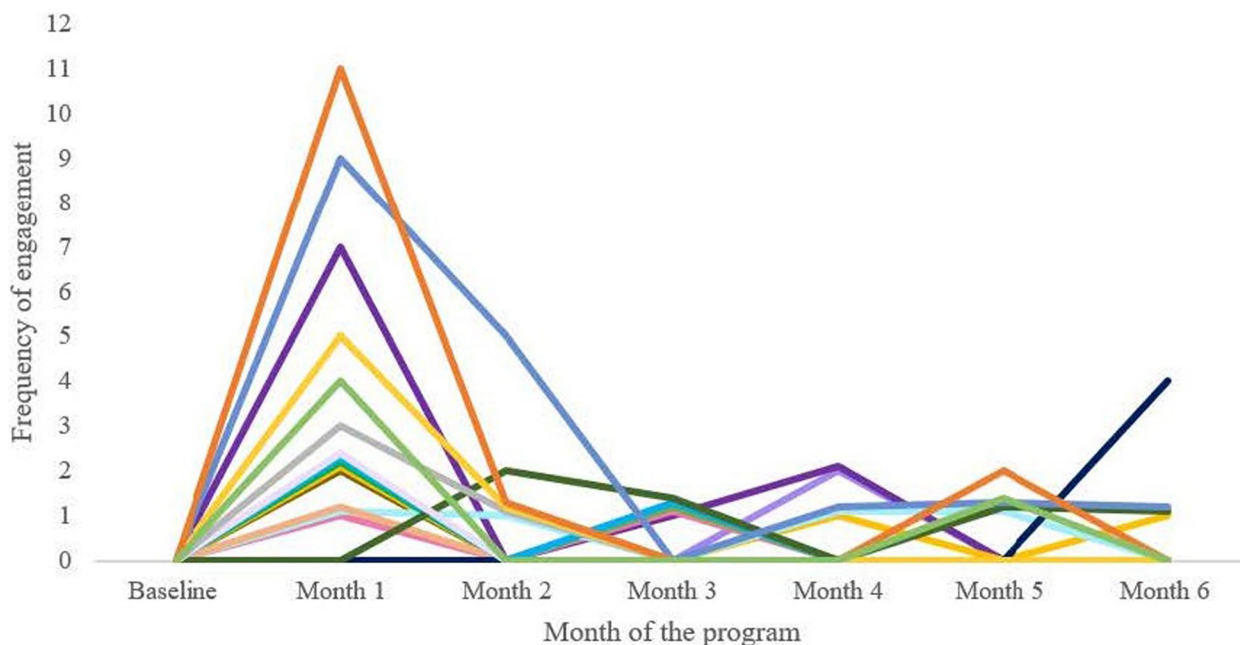
Fig. 3 Engagement with the nutrition app: Of 30 participants who chose the app, *n* = 18 (60%) engaged with it over the 6-month study duration. Each of the coloured lines represents an individual participant engagement. Nine participants (30%) did not engage and for 10% (*n* = 3) engagement could not be determined

Intention (or planned behaviour) is a significant determinant of behaviour change [37] however a substantial intention-behaviour gap has been identified in diet and exercise interventions [37, 38]. Patient choice of intervention was a novel aspect of this trial and indicated intention of engagement. Previous literature investigating the effect of patient choice on health outcomes have shown positive results, with particular improvements in intervention adherence and clinical outcome measures [15, 16]. However, the gap between digital health option selection at baseline and the subsequent low engagement with those options suggests a similar disconnect between intention and implementation of behaviour change. The most selected digital health options at baseline in the current study were the nutrition app and video consultation sessions. However, there was considerable variability in engagement with the nutrition app and lower than expected attendance to video consultations through the study period. The frequency of engagement with the nutrition app peaked in the first month of the intervention with limited engagement thereafter. It remains unclear what an appropriate engagement target would be needed for sustained behaviour change. The design of 'set and forget' text messages to deliver digital health messages and 24-h wear time for activity monitors appears to reduce intention-behaviour gap. This may be due to the automated or continuous nature of delivery which has been shown to improve adherence to digital

health services [39]. In the current study, health-related text messages were individualised to participant condition and delivered at set times during the week. Given the tangible effect of personalisation on adherence to health interventions, this approach may have positively enhanced user engagement[39]. The individualised reminders (including just-in-time-adaptive reminders to move), real-time feedback and passive/automated data collection provided by wearable activity monitors may contribute to improved engagement.

A recent meta-analysis investigating the effectiveness and feasibility of video consultation exercise interventions in chronic disease settings found a lack of standardised reporting of attendance data, making it difficult to determine typical attendance rates in other clinical trial settings [40]. In less medically complex groups, attendance to video consultations ranges from 58 to 79% of scheduled sessions [41, 42]. Whilst in highly controlled research settings, attendance may be an appropriate reflection of patient engagement, for participants in this trial, many experienced planned and unplanned hospital admissions over the trial period which impacted on attendance with the video consultations and may not have reflected a lack of intended engagement with the service. Further investigation of factors impacting intention-behaviour gap in this cohort are warranted.

This trial was designed to enable patient-centred delivery of care, so some heterogeneity in intervention

Table 5 Continuous clinical outcome results

ANCOVA Variable	INT n	INT Baseline	INT Change (Week 26)	COM n	COM Baseline	COM Change (Week 26)	Adjusted Mean Difference in Change Score INT – COM (95%CI)	Effect Size (η^2) (p-value)^	Magnitude of between-group effect
Clinical parameters									
Body mass (kg)^	30	87.0 [81.5 to 103.3]	0.2 [1.7 to 2]	27	89.4 [82.6 to 112.5]	-1.3 [-3.8 to 3.5]	n.a	1.59# (p=0.21)	n.a
WC (cm)	25	109.9±14.7	-1.5±4.4	21	114.2±17.2	-2.9±6.8	1.4 (-2.1 to 4.8)	0.01 (p=0.42)	small
SBP (mmHg)	29	133.2±16.4	4.3±18.6	27	133.2±15.1	-0.4±16.2	4.7 (-3.3 to 12.8)	0.02 (p=0.25)	small/moderate
DBP (mmHg)	29	81.6±8.1	-0.1±9.0	27	85.3±10.6	-1.2±11.4	-1.2 (-5.8 to 3.4)	0.00 (p=0.62)	negligible
Resting HR (bpm)	24	79.9±14.0	-3.4±12.0	25	80.5±11.1	-0.2±13.1	-3.3 (-9.9 to 3.3)	0.02 (p=0.32)	small/moderate
Blood composition (fasted)									
BGL (mmol/L)	28	6.0±1.8	0.2±1.6	28	6.0±1.4	0.1±1.1	0.1 (-0.7 to 0.8)	0.00 (p=0.81)	negligible
Triglycerides (mmol/L)^	19	1.7 [1.4 to 2.3]	-0.2 [-0.3 to 0.45]	16	1.8 [1.6 to 3.0]	-0.3 [-0.8 to 0.6]	n.a	0.23# (p=0.64)	n.a
HDL (mmol/L)	18	1.2±0.4	0.0±0.2	14	1.1±0.3	0.0±0.2	0.0 (-0.2 to 0.1)	0.00 (p=0.72)	negligible
Metabolic severity									
MetSSS	15	3.35±1.84	0.4±1.1	11	3.68±1.83	-0.4±2.1	0.78 (-0.52 to 2.07)	0.04 (p=0.23)	small/moderate
Exercise capacity									
6MWT (m)	19	475.8±88.2	14.6±64.1	20	462.0±94.2	33.9±41.3	-16.8 (-50.6 to 16.9)	0.02 (p=0.32)	small/moderate
Neuromuscular fitness									
5xSTS (s)	21	14.1±3.4	-0.4±3.3	20	16.6±5.0	-1.9±2.8	1.2 (-0.8 to 3.2)	0.02 (p=0.23)	small/moderate
Dominant HGS (kg)	21	34.8±12.7	-1.7±6.7	20	36.7±12.8	-0.2±6.3	-1.8 (-5.7 to 2.2)	0.02 (p=0.37)	small/moderate
Non-dominant HGS (kg)	21	33.7±11.7	-2.4±6.5	20	33.2±11.5	0.6±6.1	-2.9 (-6.8 to 0.9)	0.05 (p=0.13)	small/moderate
Muscular pain									
MNMQ (pain intensity score)	27	15.0±14.5	2.6±12.1	24	14.0±12.3	-0.3±10.3	3.0 (-3.3 to 9.4)	0.02 (p=0.34)	small/moderate

Table 5 (continued)

	INT			COM			Mean Difference (95%CI) INT—COM	Effect size (d) (p-value)^	Magnitude of between-group effect
	n	Value		n	Value				
Sleep quality									
PSQI (total score)	27	9.0±4.2	0.2±2.8	24	8.3±4.0	-0.3±2.7	0.7 (-0.8 to 2.2)	0.02 (p=0.37)	small/moderate
Quality of life									
EQ-5D-5L (index value)	27	0.783 [0.716 to 0.898]	-0.006 [-0.121 to 0.075]	25	0.746 [0.542 to 0.859]	0 [-0.128 to 0.141]	n.a	0.25# (p=0.62)	n.a
EQ-5D-5L (VAS)	26	63.6±22.7	6.5±18.9	25	62.3±18.6	10.0±17.8	-2.8 (-10.5 to 5.0)	0.01 (p=0.48)	small
Fatigue									
FACIT (total score)	27	32.6±12.5	-0.4±8.9	24	35.3±11.5	2.8±8.1	-4.0 (-8.5 to 0.6)	0.05 (p=0.08)	small/moderate

t-test Variable	INT		COM		Mean Difference (95%CI) INT—COM	Effect size (d) (p-value)^	Magnitude of between-group effect
	n	Value	n	Value			
Physical activity §							
MVPA mins/week	27	111±65	29	102±87	9 (-32 to 50)	0.12 (p=0.66)	small
Steps/day (Fitbit)	27	7537±3924	29	7616±3608	-79 (-2104 to 1947)	-0.02 (p=0.94)	small

Data presented in mean±SD unless otherwise stated

Abbreviations: INT Intervention, *COM* Comparator, *n* Number, η^2 Eta-squared, *CI* Confidence interval, *6MWT* 6-min walk test, *m* Metre, *5xSTS* Repeated chair stand test, *s* Second, *kg* Kilogram, *n.a.* Not available due to variable not being generated by quades nonparametric ANCOVA, *MetSSS* Metabolic syndrome severity score, *HGS* Hand grip strength, *HR* Heart rate, *bpm* Beats per minute, *SBP* Systolic blood pressure, *mmHg* Millimetre of mercury, *DBP* Diastolic blood pressure, *WC* Waist circumference, *cm* Centimetre, *mmol/L* Millimoles per litre, *HDL* High-density lipoprotein cholesterol, *BGL* Fasting blood glucose, *PSQI* Pittsburgh sleep quality index, *FACIT* Functional assessment of chronic illness therapy – fatigue scale, *d* Cohens d, *MVPA* Moderate to vigorous intensity physical activity

^ Median [IQR]

F statistic generated by quades nonparametric ANCOVA

§ Data collected via wearable activity monitor (Fitbit®)

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 14 of 18

Table 6 Changes in dietary quality intake variables between groups via ANCOVA

Variable	INT (*n* = 24)		COM (*n* = 20)		Adjusted Mean Difference in Change Score INT – COM (95%CI)	Effect Size (η^2) (*p*-value)^	Magnitude of between-group effect
	Baseline	Change (Week 26)	Baseline	Change (Week 26)			
Food groups							
Grains (serves/d)	5.2 ± 2.3	0.8 ± 2.4	6.0 ± 2.6	-0.7 ± 1.9	1.3 (-0.03 to 2.6)	0.08 (*p* = 0.05)	small/moderate
Wholegrain (serves/d)	1.6 ± 1.4	-0.2 ± 1.3	1.7 ± 1.5	0.0 ± 1.3	-0.4 (-1.1 to 0.3)	0.02 (*p* = 0.28)	small/moderate
Grains, wholegrain proportion (%)	31.5 ± 22.6	-8.7 ± 25	32.6 ± 22.3	8.1 ± 18.5	-17.3 (-29.9 to -4.7)	**0.13 (*p* = 0.01)**	large
Fruit (serves/d)^	0.7 [0.3 to 1.4]	0.4 [-0.1 to 1.0]	0.5 [0.3 to 1.5]	0.0 [-0.4 to 1.1]	n.a	1.09# (*p* = 0.30)	n.a
Vegetables (serves/d)^	3.1 [2.0 to 5.8]	0.0 [-1.8 to 0.5]	2.9 [1.5 to 4.4]	0.3 [-2.5 to 1.8]	n.a	0.12# (*p* = 0.73)	n.a
Legumes (serves/wk)^	0.0 [0.0 to 0.0]	0.0 [0.0 to 0.0]	0.0 [0.0 to 0.0]	0.0 [0.0 to 0.9]	n.a	3.81# (*p* = 0.06)	n.a
Red meat (serves/wk)^	4.5 [2.0 to 7.4]	1.2 [-4.6 to 2.2]	3.1 [0.2 to 8.4]	2.1 [-3.1 to 5.1]	n.a	1.51# (*p* = 0.23)	n.a
Processed meat (serves/wk)^	1.6 [0.0 to 4.1]	-0.1 [-1.7 to 0.0]	1.0 [0.1 to 2.89]	0.1 [-1.2 to 1.0]	n.a	1.62# (*p* = 0.21)	n.a
Fish and seafood (serves/wk)^	0.0 [0.0 to 2.7]	0.0 [-0.3 to 2.1]	0.0 [0.0 to 1.4]	0.0 [0.0 to 0.1]	n.a	1.50# (*p* = 0.23)	n.a
Nuts and seeds (serves/wk)^	0.4 [0.0 to 2.5]	0.0 [-1.3 to 0.2]	2.6 [0.0 to 5.2]	0.1 [-3.3 to 3.0]	n.a	1.24# (*p* = 0.27)	n.a
Dairy foods (serves/d)	2.0 ± 1.7	-0.2 ± 1.8	1.8 ± 1.0	0.1 ± 1.2	-0.2 (-0.9 to 0.5)	0.00 (*p* = 0.63)	negligible
Unsaturated oils (tsp/d)	6.2 ± 2.7	1.5 ± 3.4	7.9 ± 4.3	-1.6 ± 4.3	2.2 (0.1 to 4.3)	**0.07 (*p* = 0.04)**	small/moderate
Solid fats (tsp/d)	6.0 ± 2.2	-1.3 ± 4.1	7.0 ± 4.6	-0.3 ± 5.4	-0.6 (-3.3 to 5.3)	0.00 (*p* = 0.67)	negligible
Nutrients							
Energy (kJ/d)	8607.3 ± 2545.5	-301.7 ± 2436.6	8194.5 ± 2506.4	-711.8 ± 2646.6	447.6 (-11,071.3 to 1966.4)	0.00 (*p* = 0.56)	negligible
Fibre (g/d)	22.3 ± 7.8	-0.7 ± 0.8	23.0 ± 10.3	-1.1 ± 11.3	0.0 (-5.3 to 5.3)	0.00 (*p* = 0.99)	negligible
Added sugar (tsp/d)^	8.0 [2.9 to 15.0]	-2.0 [-8.3 to 5.3]	5.0 [2.1 to 9.5]	-2.1 [-6.3 to 1.8]	n.a	1.29# (*p* = 0.26)	n.a
Alcohol (SD/wk)^	0.0 [0.0 to 4.3]	0.0 [-0.2 to 0.0]	0.0 [0.0 to 0.0]	0.0 [0.0 to 0.0]	n.a	0.40# (*p* = 0.53)	n.a
% kJ from solid fat, alcohol and added sugar^	24.6 [30.4 to 37.4]	-3.9 [-12.2 to 4.3]	18.6 [24.7 to 36.7]	-1.5 [-6.2 to 5.9]	n.a	0.07# (*p* = 0.79)	n.a

Data presented in mean ± SD unless otherwise stated

Food group explanations: processed meat, frankfurters, sausage, corned beef, cured ham and luncheon meat made from beef, pork, poultry; unsaturated oils, fats naturally occurring in nuts, seeds, avocado, seafoods, and unhydrogenated vegetable oils; excludes palm oil and coconut oil; solid fats, fats naturally occurring in meat, poultry, eggs, dairy, fully or partially hydrogenated oils, shortening, palm oil and coconut oil

Abbreviations: INT intervention, *COM* comparator, *n* number, *η^2* eta-squared, *CI* confidence interval, *n.a.* Not available due to variable not being generated by quades nonparametric ANCOVA, */d* per day, */wk* per week, *SD* standard drinks, *tsp* teaspoons

^ Median [IQR]. #*F* statistic generated by quades nonparametric ANCOVA

exposure is to be expected. The intervention increased the exposure of participants to exercise and diet professionals, with a higher number of review appointments than the comparator group. These sessions were in addition to 24-h access to digital health resources via text messages, online content and smart phone applications.

Greater accessibility to healthcare services is a commonly reported benefit of digital health interventions [43, 44]. This is of particular importance for those in regional or rural areas, who may have limited access to in-person specialist services and digital health may go some way in addressing issues of access equity [45].

There were no study-related serious adverse events associated with the intervention. This was despite low baseline levels of physical activity with frequent pain, profound fatigue and significant metabolic disturbance. Whilst clinician-perceived safety risk for patients with complex multimorbidity is a barrier for implementing digital health exercise services [43], there is no evidence for increased long term adverse events associated with these interventions [40, 46]. In a report from Australian allied health professionals, safety concerns (including vital sign monitoring, injury and instruction comprehension) were raised amongst clinicians leading video consultation services during the COVID-19 pandemic [43]. In contrast, patients reported high levels of satisfaction with remote services with minimal safety concerns [43]. The relatively small number of mild to moderate musculoskeletal injuries is noteworthy for future development of digital health interventions incorporating exercise [47].

Many in-person clinical measures that are widely used to assess effectiveness of diet and exercise interventions are not easily utilised in a remote monitoring environment [48]. This is of particular importance for outcome monitoring of patients who do not frequently attend in-person outpatient services. Missing data rates in the current study highlight this, where outcomes that required in-person measurements, such as the MetSSS and the 6-min walk test (where 61% and 40% of participants respectively had missing data), were constrained by the need for physical attendance. This has implications for the transition to virtual service delivery, which requires confidence in the outcome measures utilised for clinical monitoring [48]. Contemporary literature suggests that digital health interventions in chronic disease may improve clinical outcomes [11, 40]. However, further original research needs to be completed to fully understand the ideal implementation strategies in different contexts. Exploration of appropriate alternative measures that can be performed and monitored remotely are critical for the future of digital health service design.

Clinical outcome measures were underpowered due to sample size. However, there was no evidence to suggest any significant between group differences for change in any clinical variable adjusted for baseline. Contemporary literature suggests that digital health interventions may improve clinical outcomes [11, 40]. However, further robust original research must be completed to fully understand the ideal implementation strategies in

different contexts. All participants received a wearable physical activity monitor and dietary advice from specialist dietitians through the study period. This design means the comparator group still received usual specialist dietetic support and may have increased physical activity more than what might be expected in usual care which, in our local context, does not typically include provision of physical activity monitoring. The provision of an activity monitor to the comparator group was justified in order to have a means to objectively monitor physical activity, and to be able to observe improvements in the intervention group above that of simply wearing the activity monitor. Meeting recommended MVPA targets of 150 min per week remains a challenge with both groups meeting target only around 25% of the time each week.

There was a positive net-benefit for the intervention group due to the mechanism for funding group consultations in the local context. Procuring technology (e.g. purchasing wearable activity monitors) were the largest cost in the intervention group. These costs were offset by the group consultation remuneration. Therefore, the net-benefit and return on investment are specific to the local context and may not be transferrable to other settings. Incremental costs associated with the technology items may decrease as services are scaled, reducing the overall intervention cost. Future research could investigate societal benefits from telehealth interventions associated with productivity, reduced travel and improved access to care [12, 49]. This may equate to improved health equity.

The results of this trial should be viewed in the context of the strengths and limitations of the study design and its implementation. The pre-determined feasibility criterion was a strength of the analysis. The RCT design which incorporated patient choice in intervention exposure is novel and the complex cohort recruited are typically under-represented in clinical trials. The digital health intervention enabled diet and exercise video consultations to be offered in a unified complex chronic condition service model. This dismantled the specialist-centric siloed approach to care [3, 5]. COVID-19 disruptions negatively impacted the study in a number of ways: i) reduced outpatient activity and referrals to dietetics limited recruitment opportunities; ii) the fidelity of usual care received by the comparator group may have been compromised as they were potentially exposed to more digital health assisted service delivery than usual (e.g. receiving dietitian review via telephone when clinics were closed); iii) exercise and food habits and choices were potentially influenced by public health stay-at-home orders and nationwide disruption in food production and delivery systems and, iv) reduced physical attendance at clinic resulted in high rates of missing data, particularly those requiring

in-person assessment (e.g. MetSSS, 6MWT) therefore limiting statistical power to assess clinical outcomes. Feasibility trials play an important role in informing the design of larger trials. The data from the sample of 67 participants in this study gives a good estimate of change in metabolic outcomes which are required for calculating sample sizes necessary for larger innovative trial designs which may also require adaptive features to support patient choice and individual tailoring of services. The use of monitoring devices that provide real time feedback to participants need to be carefully considered in future study designs. Whilst some studies suggest the addition of monitoring devices provide only modest impacts on behaviours compared to self-monitoring [50], the potential impact on behaviour within usual care control groups (i.e. reducing the likelihood of detecting a difference between groups) must be considered. As much of the previous research on the impact of self-monitoring physical activity on physical activity behaviour has focussed on otherwise healthy cohorts, more work is needed to determine if this is sufficient for change in people with complex chronic illness [51]. Whilst the delivery of the trial was feasible, there were concerns related to engagement and adherence with some of the technology options in this cohort. A broader evaluation of participant reported acceptability of technology-assisted service delivery is detailed elsewhere [52]. Further refinement of systems to support digital health service delivery and strategies to better individualise care may be needed to enhance adherence and fidelity prior to larger clinical trials in this patient cohort.

Conclusions

This study evaluated the implementation of digital health diet and exercise services for people with complex chronic conditions being managed in a tertiary hospital outpatient setting. It was found that digital health diet and exercise support delivered as a unified complex chronic disease service is feasible in a tertiary hospital outpatient setting. Digital health offers the opportunity to increase contact with health professionals whilst generating efficiencies in models of care and improving health access equity. Feasibility was confirmed in this study. Although digital health offers the opportunity to increase contact with health professionals whilst generating efficiencies in models of care and generating more activity-based funding return on investment, concerns around digital health engagement and adherence to intervention strategies were noted in this cohort. Further work to identify adherence-building strategies are needed to improve engagement.

Abbreviations

SRSAE	Study-related serious adverse event
CKD	Chronic kidney disease
SAE	Serious adverse event
AE	Adverse event
MetSSS	Metabolic syndrome severity score
IPAQ-SF	International physical activity questionnaire – short form
MVPA	Moderate-vigorous physical activity
6MWT	6-Minute walk test
5xSTS	Repeated sit-to-stand chair stand test
HGS	Hand grip strength
MNMQ	Modified Nordic musculoskeletal questionnaire
FACIT	Functional assessment of chronic illness therapy scale
PSQI	Pittsburgh sleep quality index
EQ-5D-5L	EuroQol-5D five level scale
BMI	Body mass index
ANCOVA	Analysis of covariance
COVID-19	Coronavirus disease SARS CoV-2 virus
RCT	Randomised controlled trial

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12913-024-11383-4.

Supplementary Material 1.

Authors' contributions

IJH, GAM, KLC, JSC, NMI, MMC, HLM, DKJ, and SEK contributed to study conception. RCCB, MMC, JTK, AB, GAM, SEK, JSC, NMI, KLC, HMS, and IJH contributed to study design. RCCB, MMC, JTK, AB, NWB, GAM, SEK, JSC, DKJ, NMI, KLC, HLM, HMS, and IJH provided input into the development of the intervention and assessment resources and materials. RCCB, SEK, DKJ, HLM, AB, MMC, LW, CLS and IJH collected and analysed data. RCCB, SEK, DKJ, HLM, AB, MMC, LW, JSC, CLS and IJH interpreted data. RCCB, AB, HLM and IJH created the first draft of the manuscript. All authors critically revised the manuscript. All authors saw and approved each revised manuscript, including the final version.

Availability of data and materials

No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This trial has been approved by the Metro South Human Research Ethics Committee (trial number: HREC/2019/QMS/58285) and the University of Queensland Human Research Ethics Committee (clearance number: 2020000127). The trial adheres to the Helsinki declaration and is prospectively registered with Australian New Zealand Clinical Trial Registry (anzctr.org.au) identifier: ACTRN12620001282976. Participant information and consent forms were provided in advance of baseline assessment, and written informed consent was obtained at in-person attendance at the baseline appointment.

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 17 of 18

Author details
[1]School of Human Movement and Nutrition Sciences, The University of Queensland, Brisbane, Australia. [2]Centre for Research On Exercise, Physical Activity and Health, The University of Queensland, Brisbane, Australia. [3]Department of Kidney and Transplant Services, Princess Alexandra Hospital, Brisbane, Australia. [4]Faculty of Medicine, The University of Queensland, Brisbane, Australia. [5]Department of Nutrition and Dietetics, Princess Alexandra Hospital, 199 Ipswich Road Woolloongabba, Brisbane 4012, Australia. [6]Centre for Functioning and Health Research, Metro South Health, Brisbane, Australia. [7]Centre for Online Health, The University of Queensland, Brisbane, Australia. [8]Centre for Health Services Research, The University of Queensland, Brisbane, Australia. [9]Food & Mood Centre, Institute for Mental and Physical Health and Clinical Translation, Deakin University, Geelong, Australia. [10]Department of Gastroenterology and Hepatology, Princess Alexandra Hospital, Brisbane, Australia. [11]School of Applied Psychology, Griffith University, Brisbane, Australia. [12]Menzies Health Institute Queensland, Griffith University, Gold Coast, Australia. [13]Centre for Mental Health, Griffith University, Brisbane, Australia. [14]Healthcare Excellence and Innovation, Metro North Health, Brisbane, Australia.

References
1. Scholze J, Alegria E, Ferri C, Langham S, Stevens W, Jeffries D, Uhl-Hochgraeber K. Epidemiological and economic burden of metabolic syndrome and its consequences in patients with hypertension in Germany, Spain and Italy; a prevalence-based model. BMC Public Health. 2010;10:1–12.
2. Yamaoka K, Tango T. Effects of lifestyle modification on metabolic syndrome: a systematic review and meta-analysis. BMC Med. 2012;10:138.
3. Hickman IJ, Coran D, Wallen MP, Kelly J, Barnett A, Gallegos D, Jarrett M, McCoy SM, Campbell KL, Macdonald GA. Back to life'-using knowledge exchange processes to enhance lifestyle interventions for liver transplant recipients: a qualitative study. Nutr Diet. 2019;76(4):399–406.
4. Howden EJ, Coombes JS, Strand H, Douglas B, Campbell KL, Isbel NM. Exercise training in CKD: efficacy, adherence, and safety. Am J Kidney Dis. 2015;65(4):583–91.
5. Mayr HL, Savill H, Law L, Campbell KL, Hill J, Palmer M, Hickman IJ, Kelly JT. We work in silos: exploring clinicians' perspectives on the dietary management of coronary heart disease and type 2 diabetes in an Australian public hospital and community health service. Nutr Diet. 2023;80(3):307–19.
6. Kelly JT, Campbell KL, Hoffmann T, Reidlinger DP. Patient experiences of dietary management in chronic kidney disease: a focus group study. J Ren Nutr. 2018;28(6):393–402.
7. Bonner A, Gillespie K, Campbell KL, Corones-Watkins K, Hayes B, Harvie B, Kelly JT, Havas K. Evaluating the prevalence and opportunity for technology use in chronic kidney disease patients: a cross-sectional study. BMC Nephrol. 2018;19(1):28.
8. Cotugno JD, Ferguson M, Harden H, Colquist S, Stack AA, Zimmerman JI, Russell AW, Ball LE, Hickman IJ. "I wish they could be in my shoes": patients' insights into tertiary health care for type 2 diabetes mellitus. Patient Prefer Adherence. 2015;9:1647–55.
9. Barnett A, Campbell KL, Mayr HL, Keating SE, Macdonald GA, Hickman IJ. Liver transplant recipients' experiences and perspectives of a telehealth-delivered lifestyle programme: a qualitative study. J Telemed Telecare. 2021;27(9):590–8.
10. Hickman IJ, Hannigan AK, Johnston HE, Elvin-Walsh L, Mayr HL, Staudacher HM, Barnett A, Stoney R, Salisbury C, Jarrett M, Reeves MM, Coombes JS, Campbell KL, Keating SE, Macdonald GA. Telehealth-delivered, cardioprotective diet and exercise program for liver transplant recipients: a randomized feasibility study. Transplant Direct. 2021;7(3):e667.
11. Barnett A, Wright C, Stone C, Ho NY, Adhyaru P, Kostjasyn S, Hickman IJ, Campbell KL, Mayr HL, Kelly JT. Effectiveness of dietary interventions delivered by digital health to adults with chronic conditions: systematic review and meta-analysis. J Hum Nutr Diet. 2023;36(3):632–56.
12. Kelly JT, Law L, De Guzman KR, Hickman IJ, Mayr HL, Campbell KL, Snoswell CL, Erku D. Cost-effectiveness of telehealth-delivered nutrition interventions: a systematic review of randomized controlled trials. Nutr Rev. 2023;81(12):1599–611.
13. Law L, Kelly JT, Savill H, Wallen MP, Hickman IJ, Erku D, Mayr HL. Cost-effectiveness of telehealth-delivered diet and exercise interventions: a systematic review. J Telemed Telecare. 2022;30(5):420–37.
14. Taylor ML, Thomas EE, Vitangcol K, Marx W, Campbell KL, Caffery LJ, Haydon HM, Smith AC, Kelly JT. Digital health experiences reported in chronic disease management: an umbrella review of qualitative studies. J Telemed Telecare. 2022;28(10):705–17.
15. Clark NM, Janz NK, Dodge JA, Mosca L, Lin X, Long Q, Little RJ, Wheeler JR, Keteyian S, Liang J. The effect of patient choice of intervention on health outcomes. Contemp Clin Trials. 2008;29(5):679–86.
16. Delevry D, Le QA. Effect of treatment preference in randomized controlled trials: systematic review of the literature and meta-analysis. Patient. 2019;12(6):593–609.
17. Brown RCC, Jegatheesan DK, Conley MM, Mayr HL, Kelly JT, Webb L, Barnett A, Staudacher HM, Burton NW, Isbel NM, Macdonald GA, Campbell KL, Coombes JS, Keating SE, Hickman IJ. Utilizing Technology for Diet and Exercise Change in Complex Chronic Conditions Across Diverse Environments (U-DECIDE): protocol for a randomized controlled trial. JMIR Res Protoc. 2022;11(7):e37556.
18. Eldridge SM, Chan CL, Campbell MJ, Bond CM, Hopewell S, Thabane L, Lancaster GA, Group Pc. CONSORT statement: extension to randomised pilot and feasibility trials. BMJ. 2010;2016(355):i5239.
19. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D, Altman DG, Barbour V, Macdonald H, Johnston M, Lamb SE, Dixon-Woods M, McCulloch P, Wyatt JC, Chan AW, Michie S. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. BMJ. 2014;348:g1687.
20. Alberti KG, Eckel RH, Grundy SM, Zimmet PZ, Cleeman JI, Donato KA, Fruchart JC, James WP, Loria CM, Smith SC Jr., International Diabetes Federation Task Force on Epidemiology and Prevention, Hational Heart, Lung, and Blood Institute, American Heart Association, World Heart Federation, International Atherosclerosis Society, International Association for the Study of Obesity. Harmonizing the metabolic syndrome: a joint interim statement of the International Diabetes Federation Task Force on Epidemiology and Prevention; National Heart, Lung, and Blood Institute; American Heart Association; World Heart Federation; International Atherosclerosis Society; and International Association for the Study of Obesity. Circulation. 2009;120(16):1640.
21. Wiley JF, Carrington MJ. A metabolic syndrome severity score: a tool to quantify cardio-metabolic risk factors. Prev Med. 2016;88:189–95.
22. Craig CL, Marshall AL, Sjostrom M, Bauman AE, Booth ML, Ainsworth BE, Pratt M, Ekelund U, Yngve A, Sallis JF, Oja P. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exerc. 2003;35(8):1381–95.
23. Coombes J, Skinner T. ESSA's student manual for health, exercise and sport assessment-ebook. Chatswood: Elsevier Health Sciences; 2014.
24. Kuorinka I, Jonsson B, Kilbom A, Vinterberg H, Biering-Sorensen F, Andersson G, Jorgensen K. Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms. Appl Ergon. 1987;18(3):233–7.
25. Herdman M, Gudex C, Lloyd A, Janssen M, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Qual Life Res. 2011;20(10):1727–36.
26. Webster K, Cella D, Yost K. The Functional Assessment of Chronic Illness Therapy (FACIT) measurement system: properties, applications, and interpretation. Health Qual Life Outcomes. 2003;1:79.
27. Buysse DJ, Reynolds CF 3rd, Monk TH, Berman SR, Kupfer DJ. The Pittsburgh Sleep Quality Index: a new instrument for psychiatric practice and research. Psychiatry Res. 1989;28(2):193–213.
28. Queensland Health. Queensland public hospital services purchasing and funding models. https://www.health.qld.gov.au/system-governance/health-system/managing/funding-model. Accessed 02/05/2024.
29. Billingham SA, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered

Brown *et al. BMC Health Services Research*   (2024) 24:935

Page 18 of 18

in the United Kingdom clinical research network database. BMC Med Res Methodol. 2013;13:104.

30. Flynn A, Preston E, Dennis S, Canning CG, Allen NE. Home-based exercise monitored with telehealth is feasible and acceptable compared to centre-based exercise in Parkinson's disease: a randomised pilot study. Clin Rehabil. 2021;35(5):728–39.

31. Kelly JT, Warner MM, Conley M, Reidlinger DP, Hoffmann T, Craig J, Tong A, Reeves M, Johnson DW, Palmer S, Campbell KL. Feasibility and acceptability of telehealth coaching to promote healthy eating in chronic kidney disease: a mixed-methods process evaluation. BMJ Open. 2019;9(1):e024551.

32. Vacha-Haase T, Thompson B. How to estimate and interpret various effect sizes. J Couns Psychol. 2004;51(4):473.

33. Jhamb M, Liang K, Yabes J, Steel JL, Dew MA, Shah N, Unruh M. Prevalence and correlates of fatigue in chronic kidney disease and end-stage renal disease: are sleep disorders a key to understanding fatigue? Am J Nephrol. 2013;38(6):489–95.

34. Yilmaz Y, Toraman AE, Alp C, Dogan Z, Keklikkiran C, Stepanova M, Younossi Z. Impairment of patient-reported outcomes among patients with non-alcoholic fatty liver disease: a registry-based study. Aliment Pharmacol Ther. 2023;57(2):215–23.

35. Yang F, Lau T, Lee E, Vathsala A, Chia KS, Luo N. Comparison of the preference-based EQ-5D-5L and SF-6D in patients with end-stage renal disease (ESRD). Eur J Health Econ. 2015;16(9):1019–26.

36. Cook R, Haydon HM, Thomas EE, Ward EC, Ross JA, Webb C, Harris M, Hartley C, Burns CL, Vivanti AP, Carswell P, Caffery LJ. Digital divide or digital exclusion? Do allied health professionals' assumptions drive use of telehealth? J Telemed Telecare. 2023;0(0):1357633X231189846. https://journals.sagepub.com/doi/10.1177/1357633X231189846.

37. Rhodes RE, Cox A, Sayar R. What predicts the physical activity intention-behavior gap? A Systematic Review Ann Behav Med. 2022;56(1):1–20.

38. McDermott MS, Oliver M, Simnadis T, Beck EJ, Coltman T, Iverson D, Caputi P, Sharma R. The theory of planned behaviour and dietary patterns: a systematic review and meta-analysis. Prev Med. 2015;81:150–6.

39. Jakob R, Harperink S, Rudolf AM, Fleisch E, Haug S, Mair JL, Salamanca-Sanabria A, Kowatsch T. Factors influencing adherence to mhealth apps for prevention or management of noncommunicable diseases: systematic review. J Med Internet Res. 2022;24(5):e35371.

40. Brown RC, Coombes JS, Jungbluth Rodriguez K, Hickman IJ, Keating SE. Effectiveness of exercise via telehealth for chronic disease: a systematic review and meta-analysis of exercise interventions delivered via videoconferencing. Br J Sports Med. 2022;56:1042–52.

41. Clark DO, Keith N, Weiner M, Xu H. Outcomes of an RCT of videoconference vs. in-person or in-clinic nutrition and exercise in midlife adults with obesity. Obes Sci Pract. 2019;5(2):111–9.

42. Fischer M, Weimann T, Oberander N, Schupitza L, Hosel J, Weimann A. Remote treatment successfully delivers a usual care weight loss and lifestyle intervention in adults with morbid obesity. Ann Nutr Metab. 2022;78(6):328–35.

43. Filbay S, Hinman R, Lawford B, Fry R, Bennell K. Telehealth by allied health practitioners during the COVID-19 pandemic: an Australian wide survey of clinicians and clients. Melbourne: The University of Melbourne; 2021.

44. Lampickiene I, Davoody N. Healthcare professionals' experience of performing digital care visits-A scoping review. Life (Basel). 2022;12(6):913.

45. Kelly JT, Jegatheesan DK, Dawson J, Barnett A, Khor BH, Chang AR, Carrero JJ, Campbell KL. Are digital health technologies and models of nutrition care the future of chronic kidney disease management? J Ren Nutr. 2023;33(6S):S80–7.

46. Chan C, Yamabayashi C, Syed N, Kirkham A, Camp PG. Exercise telemonitoring and telerehabilitation compared with traditional cardiac and pulmonary rehabilitation: a systematic review and meta-analysis. Physiother Can. 2016;68(3):242–51.

47. Zangger G, Bricca A, Liaghat B, Juhl CB, Mortensen SR, Andersen RM, Damsted C, Hamborg TG, Ried-Larsen M, Tang LH, Thygesen LC, Skou ST. Benefits and harms of digital health interventions promoting physical activity in people with chronic conditions: systematic review and meta-analysis. J Med Internet Res. 2023;25:e46439.

48. Keating SE, Barnett A, Croci I, Hannigan A, Elvin-Walsh L, Coombes JS, Campbell KL, Macdonald GA, Hickman IJ. Agreement and reliability of clinician-in-clinic versus patient-at-home clinical and functional assessments: implications for telehealth services. Arch Rehabil Res Clin Transl. 2020;2(3):100066.

49. Barnes KA, Szewczyk Z, Kelly JT, Campbell KL, Ball LE. How cost-effective is nutrition care delivered in primary healthcare settings? A systematic review of trial-based economic evaluations. Nutr Rev. 2022;80(6):1480–96.

50. Vetrovsky T, Borowiec A, Jurik R, Wahlich C, Smigielski W, Steffl M, Tufano JJ, Drygas W, Stastny P, Harris T, Malek L. Do physical activity interventions combining self-monitoring with other components provide an additional benefit compared with self-monitoring alone? A systematic review and meta-analysis. Br J Sports Med. 2022;56(23):1366–74.

51. Chia GLC, Anderson A, McLean LA. Behavior change techniques incorporated in fitness trackers: content analysis. JMIR Mhealth Uhealth. 2019;7(7):e12768.

52. Barnett A, Catapan SC, Jegatheesan DK, Conley MM, Keating SE, Mayr HL, Webb L, Brown RCC, Coombes JS, Macdonald GA, Isbel NM, Burton NW, Campbell KL, Hickman IJ, Kelly JT. Patients' acceptability of self-selected digital health services to support diet and exercise among people with complex chronic conditions: mixed methods study. Digital Health. 2024;10:1–14.

Publisher's Note