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Feasibility randomised controlled trial comparing TRAK-ACL digital rehabilitation intervention plus treatment as usual versus treatment as usual for patients following anterior cruciate ligament reconstruction

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ABSTRACT

Objectives To evaluate the feasibility of trialling taxonomy for the rehabilitation of knee conditions—ACL (TRAK-ACL), a digital health intervention that provides health information, personalised exercise plans and remote clinical support combined with treatment as usual (TAU), for people following ACL reconstruction.

Methods The study design was a two-arm parallel randomised controlled trial (RCT). Eligible participants were English-speaking adults who had undergone ACL reconstruction within the last 12 weeks, had access to the internet and could provide informed consent. Recruitment took place at three sites in the UK. TRAK-ACL intervention was an interactive website informed by behaviour change technique combined with TAU. The comparator was TAU. Outcomes were: recruitment and retention; completeness of outcome measures at follow-up; fidelity of intervention delivery and engagement with the intervention. Individuals were randomised using a computer-generated random number sequence. Blinded assessors allocated groups and collected outcome measures.

Results Fifty-nine people were assessed for eligibility at two of the participating sites, and 51 were randomised; 26 were allocated to TRAK-ACL and 25 to TAU. Follow-up data were collected on 44 and 40 participants at 3 and 6 months, respectively. All outcome measures were completed fully at 6 months except the Client Service Receipt Inventory. Two patients in each arm did not receive the treatment they were randomised to. Engagement with TRAK-ACL intervention was a median of 5 logins (IQR 3–13 logins), over 18 weeks (SD 12.2 weeks).

Conclusion TRAK-ACL would be suitable for evaluation of effectiveness in a fully powered RCT.

Key messages

What is already known

- Rehabilitation following Anterior Cruciate Ligament Reconstruction can be lengthy and challenging.
- Digital health interventions may provide an opportunity to improve access to care and support self-management for people following Anterior Cruciate Ligament reconstruction.

What are the new findings

- Digital health tools such as the TRAK-ACL website, may provide an opportunity to teach and reinforce the key lessons and exercises at each stage of rehabilitation, as well as engage patients through behaviour change functions.
- DHI may be crucial for patients who do not have access to physiotherapy throughout rehabilitation.
- TRAK-ACL is a digital health intervention would be suitable for evaluation of effectiveness in a full powered RCT.

BACKGROUND

ACL injury is common in the active population and can require lengthy and challenging rehabilitation.[1–3] Not all patients may have access to the physiotherapy care, information, education, exercise and knowledge needed at each stage of rehabilitation due to lack of time, experienced physiotherapists or specialist resources.[4 5] It is reported that only 55% of individuals return to competitive sport and better outcomes are associated with individuals that complete at least 6 months supervised rehabilitation.[4 6 7] However, only 30% of individuals with musculoskeletal conditions complete any rehabilitation beyond 6 months.[8] It has been argued that digital health interventions (DHIs), such as websites and apps, may provide an opportunity to improve access to care and support self-management in areas where ACL rehabilitation may be inadequately resourced.[9]

There is a lack of evidence to support the use of DHIs for patient's post-ACL reconstruction. One DHI which may be suitable

for supporting patient's post-ACL reconstruction is taxonomy for the rehabilitation of knee conditions—ACL (TRAK-ACL). TRAK-ACL stems from TRAK, an interactive for self-management support website,[10] which is based on an ontology that describes standard care for the rehabilitation of knee conditions.[11] TRAK-ACL focuses specifically on stage-by-stage rehabilitation after ACL reconstruction with the corresponding information presented using animations, videos, text and infographics. It includes a stage-by-stage exercise library and self-assessment criteria for progression. It was developed in line with the principles of the Behaviour Change Wheel, a framework for designing interventions and includes tools for self-monitoring and prompting engagement.[12] Previous studies have indicated the acceptability of TRAK-ACL to both patients and clinicians as an adjunct to care.[13 14]

Given this preliminary evidence suggesting that TRAK-ACL may be acceptable to patients and physiotherapists, and could be integrated into routine National Health Service (NHS) care, it is appropriate to determine whether the intervention is an effective and cost-effective use of NHS resources. The Medical Research Council framework for developing and evaluating complex interventions highlights the importance of feasibility studies for testing procedures, estimating recruitment and retention and determining the sample size of a future randomised controlled trial (RCT).[15] The process provides an opportunity to test the acceptability of recruitment pathways, outcome measures and uptake of the intervention to ultimately determine if a full-scale trial can be completed successfully.[16] This paper details a randomised feasibility trial of TRAK for patients following ACL reconstruction which aimed to determine the feasibility of an RCT comparing TRAK-ACL plus treatment as usual to treatment as usual (TAU). Specific objectives were to: (1) assess the feasibility of recruiting and retaining participants to the RCT; (2) assess the feasibility of gathering costings data and patient reported outcomes; (3) assess implementation and fidelity issues such as participants' and physiotherapists' engagement with the website; (4) assess engagement with the mechanisms of behaviour change and (5) inform the protocol for a fully powered RCT to determine the clinical and cost-effectiveness of TRAK-ACL compared with TAU.

METHODS

Design—a randomised controlled feasibility trial

This study was a parallel arm, individually randomised, feasibility RCT comparing postoperative ACL rehabilitation TAU with TAU plus TRAK-ACL. It is reported in line with the Consolidated Standards of Reporting Trials (CONSORT) reporting standards extension for pilot and feasibility trials.[17] The trial was supported by the PRIMENT clinical trials unit, a registered UK Clinical Trials Collaboration and a trial steering committee was established to oversee the trial processes.

Patient and public involvement (PPI)

This study won an award for patient involvement. TRAK-ACL was developed with a PPI group in a London NHS hospital.[13 18] The group participated in choosing and developing content for the website, ensuring the website met an acceptable standard of diversity and inclusion and the design of the feasibility study. One member of the PPI group sat on the trial steering committee. The opinions of NHS Physiotherapists contributed to the development of the TRAK-ACL website and design of the feasibility study which was informed by the findings of two previous usability and acceptability studies carried out by this team of researchers.[13 14]

Recruitment

The study took place at three NHS sites; a large University Hospital Foundation Trust, in an ethnically and socioeconomically diverse English metropolitan area (site 1), a large South of England Trust covering a mixed urban and rural population (site 2) and large University Health Board in Wales, also mixed urban and rural population (site 3). Recruitment opened in July 2018 at sites 1 and 2. Site 2 was unable to recruit patients and was closed. Site 3 was added in November 2018 and recruitment closed in March 2019. Sites 1 and 3 are reported hereafter.

Sample size

Feasibility study sample sizes are usually 50–70 participants.[19–21] However, we looked to the ACL rehabilitation clinical trial literature for estimates of retention and compliance in similar studies.[22] The literature suggested that we could expect between 20% and 25% loss to follow-up.[23 24] We therefore estimated 75% retention. We estimated that 25 in each arm would give a 95% CI of 0.60 to 0.85, suggesting that we could be 95% certain that at least 60% of the target population would remain in the trial for at least 6 months.

Randomisation

The trial statistician used computer-generated random number sequences to draw up a spread sheet where trial participant numbers could be added sequentially. Participants were allocated to the intervention or control arm by a member of the research team. Randomisation was performed after informed consent and baseline data were collected by the blinded assessor.

Intervention

Participants randomised to the intervention arm received treatment as usual (TAU) plus TRAK-ACL website. The intervention was delivered by qualified chartered physiotherapists working in the musculoskeletal out-patient setting.

TRAK-ACL website

TRAK-ACL is a DHI whose content was drawn from the literature on ACL rehabilitation. It was designed to support patients after ACL reconstruction by reinforcing teaching and exercise prescriptions given by a physiotherapist in face-to-face care. It includes an extensive

exercise library and information from the ACL literature and physiotherapists and orthopaedic surgeons experienced in managing patients with ACL reconstruction. The exercises and information were provided phase by phase (early, middle, advanced and return to sport) as videos, animations, infographs and in written text format. Interactive features such as personal goal setting, progress logs and dashboards of progress were informed by the Behaviour Change Wheel framework for intervention design and are known to promote engagement with rehabilitation behaviours.[12] The TRAK website can be accessed at: https://spas.cs.cf.ac.uk/trakacl/.

A training package was provided for physiotherapists using TRAK-ACL, including how to induct patients to TRAK-ACL. The TRAK-ACL intervention and the training programme are described in online supplemental file 1 and reported according to the Template for Intervention Description and Replication (TIDieR) guidelines.[25] Each patient was given a TRAK-ACL alphanumeric login and they were invited to seek extra support with using TRAK-ACL if needed. Tablet computers were provided to participating sites and Wi-Fi availability was ensured before the study began.

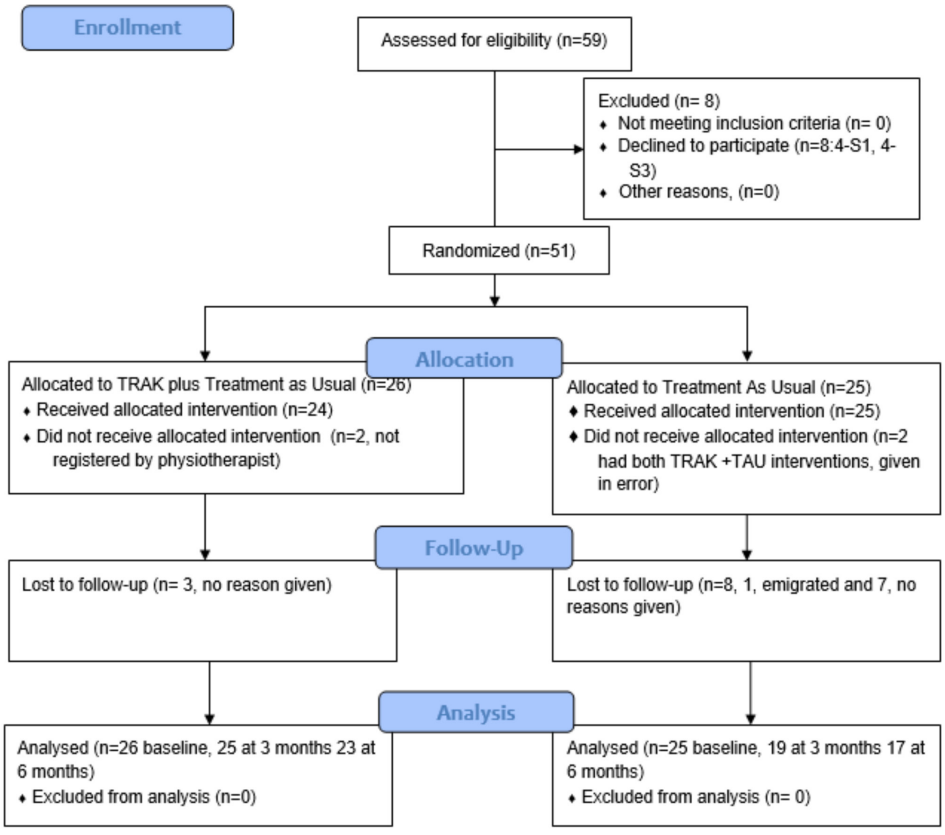
The treating physiotherapist inducted the patient on how to use the TRAK-ACL website and give the participant a login during their first face-to-face consultation. The patient was shown a playlist of exercises which were individualised to their needs by the physiotherapist. Goals were set in discussion with the patient. Both goals and exercise playlists were progressed according to the patient reaching the rehabilitation milestones. All the rehabilitation exercises were on the TRAK-ACL website.

Control group

Physiotherapy TAU varied across the included sites and is described in detail in online supplemental file 1. Common features included face-to-face time with physiotherapists, monitoring of the recovery from surgery and achievement of early rehabilitation goals. The duration of care was not restricted at either site and was expected to last for 6–12 months according to patient needs. A progression through phases of care was evident. The main difference between sites was the mode of delivery: at sites 1 and 2 care was delivered in an ACL group and at site 3 care was delivered though individual one-to-one appointments, with the option of attending a generalised lower limb class. The timing of appointments was different at each site. At sites 1 and 2 appointments were on a weekly basis dropping to fortnightly. At site 3 the scheduling was based on patient need and service capacity.

Outcome measures

The primary outcomes were feasibility outcomes (recruitment and retention) plus measures to inform the



Abbrev: S1 = Site 1, S3 = Site 2

Figure 1 CONSORT flow diagram. TAU, treatment as usual; TRAK, taxonomy for the rehabilitation of knee conditions.

Table 1 Baseline characteristics of participants

	TAU	TRAK-ACL	Site 3	Site 1
Patient characteristics	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
Age	28.4 (8.2)	30.8 (11.4)	29.0 (9.0)	29.82 (10.2)
Site	n25	n26	n10	n41
	Freq (%)	**Freq (%)**	**Freq (%)**	**Freq (%)**
Gender				
Female	12 (48.0)	11 (42.3)	3 (30.0)	20 (48.8)
Male	13 (52.0)	15 (57.7)	7 (70.0)	21 (51.2)
Ethnicity				
Asian	1 (4.0)	0 (0.0)	0 (0.0)	1 (2.4)
Asian other	0 (0.0)	1 (3.9)	0 (0.0)	1 (2.4)
Black	3 (12.0)	2 (7.7)	0 (0.0)	5 (12.2)
Mixed black and white	2 (8.0)	1 (3.9)	0 (0.0)	3 (7.3)
Mixed other	1 (4.0)	0 (0.0)	0 (0.0)	1 (2.4)
Mixed white and Asian	0 (0.0)	1 (3.9)	0 (0.0)	1 (2.4)
South Asian	0 (0.0)	2 (7.7)	0 (0.0)	2 (4.9)
White	18 (72.0)	19 (73.1)	10 (100)	27 (65.9)
Education level				
A level or equivalent*	3 (12.0)	5 (19.2)	1 (10.0)	7 (17.1)
Degree/higher degree	18 (72.0)	13 (50.0)	6 (60.0)	25 (61.0)
Diploma higher education	2 (2.0)	4 (15.4)	3 (30.0)	3 (7.3)
GCSE or equivalent†	2 (2.0)	4 (15.4)	0 (0.0)	6 (14.6)
Employment status				
Currently employed	20 (80.0)	19 (73.1)	7 (70.0)	32 (78.0)
Student	5 (20.0)	7 (26.9)	3 (30.0)	9 (22.0)

*A level: subject specific qualification for 16–18 years old.
†GCSE: subject specific qualification taken by 14–16 years old.
CONSORT, Consolidated Standard for Reporting Trials; GCSE, general certificate of seconday education; TAU, treatment as usual; TRAK-ACL, taxonomy for the rehabilitation of knee conditions—ACL.

parameters of a future trial.[26] Study outcomes were taken at baseline, 3 and 6 months.

Primary study outcomes

- Feasibility of recruitment, measured by the number of people recruited to the trial (goal of four participants per month per site).
- Feasibility of retention, measured by the number of people still in the trial at the end of the study (goal of <30% drops-outs).
- Feasibility of collecting outcome measures, measured by the number of complete outcomes that were taken for each time point (goal of >80% at 6 months).

Table 2 Allocation to TRAK-ACL

	Total	Site 1	Site 3
TRAK-ACL usage	**Freq (%)**	**Freq (%)**	**Freq (%)**
Allocated to TRAK-ACL	26 (100)	21 (81.0)	5 (19.0)
Did not receive the intervention Reason	4 (15.0)	2 (8) Technical problems prevented login and unknown	2 (7.5) Not signed up by PT
Total for analysis	22 (85.0)	19 (73.0)	3 (11.5)
Received the intervention by error Excluded from analysis	n=2	n=2	n=0

PT, Physiotherapist; TRAK-ACL, taxonomy for the rehabilitation of knee conditions—ACL.

Table 3 Retention per treatment group and across sites

Retention	Total	TAU	TRAK-ACL
	Freq (%)	Freq (%)	Freq (%)
Retention			
Baseline	51 (100)	25 (100)	26 (100)
3 months	44 (86)	19 (76)	25 (96)
6 months	40 (78)	17 (68)	23 (88)
Retention by site		**Site 3**	**Site 1**
		Freq (%)	Freq (%)
Retention			
Baseline		10 (100)	41 (100)
3 months		7 (70)	37 (90)
6 months		7 (70)	33 (80)

TAU, treatment as usual; TRAK-ACL, taxonomy for the rehabilitation of knee conditions—ACL.

- Feasibility of collecting participants' intervention usage data (goal of three or more logins per week per participant).
- Frequency of adverse events (goal <5%).

Secondary study outcomes

- Knee Injury & Osteoarthritis Outcome Score[27] (KOOS): primary outcome of a future trial. This has five patient-rated scales to assess pain, symptoms, sport, activities of daily living and knee-related quality of life.
- Stanford Self-Efficacy Questionnaire; a patient-rated six-item questionnaire to evaluate self-efficacy of condition management in people with long-term conditions.[28]
- EQ-5D-5L, a patient-rated questionnaire to evaluate health-related quality of life.[29]
- The Client Services Receipt Inventory (CSRI) health economic tool, a questionnaire to evaluate health resource use and total costs incurred by patients, their employers, families and local healthcare services.
- Strength of quadriceps, which was measured using a standard gym leg press (kg).
- Calculation of sample size for a full trial.

The KOOS was chosen as the primary outcome of a future trial on patients with ACL reconstruction using a DHI because of its ability to measure both the impact of knee injury and longer term health outcomes such as osteoarthritis.[30]

Data collection

Outcomes were collected at physiotherapy appointments at baseline, 3 and 6 months, except quadriceps strength, which was collected at site 1 at 3 and 6 months only. Outcome assessors and the lead researcher were blinded to treatment allocation but neither patients nor treating physiotherapists could be blinded as they needed to use the DHI.

Data analysis

All primary outcome measures were summarised separately by study arm. Differences in secondary outcomes between arms were estimated using linear and logistic regression. Quantitative data were analysed as follows: binary and other categorical measures such as recruitment, retention and adverse events were summarised using frequencies and percentages. Continuous measures were summarised using means and SDs (or medians and IQRs for skewed distributions). The precision of estimates was assessed using 95% CIs. Power analyses were conducted to calculate the sample size necessary to detect an effect of the intervention in a future RCT with the KOOS as the primary outcome. Intention to treat principles were applied to data for all recruited patients.[31] Progression of a full-scale trial would be considered if all of the feasibility criteria based on the primary outcomes were met.

RESULTS

Recruitment

Flow of participants through the trial is illustrated using a CONSORT flow diagram shown in figure 1. Fifty-nine people were assessed for eligibility across two sites, of whom eight people declined to participate and 51 were randomised. Of these, 26 were allocated to TRAK-ACL and 25 to TAU.

Characteristics at baseline

There were 51 study participants overall. The TAU arm and the TRAK-ACL arm were well-matched for baseline characteristics, presented in table 1.

Randomisation integrity

In TAU, two people were given the intervention by the treating physiotherapist by mistake. However, this was not known until the end of the feasibility study. Not all patients that were allocated to TRAK-ACL received the intervention. At site 3, two patients were allocated to the intervention but were never signed up to TRAK-ACL by the treating physiotherapist (table 2), although they continued to provide outcomes. At site 1, two patients were signed up to TRAK-ACL but never logged in. Hence usage data were only available for 22 participants from the TRAK-ACL group.

Retention: numbers analysed

Retention was measured by the proportion of participants providing outcome data at 3 and 6 months. In total, 44 patients were retained to the study at 3 months and 40 at 6 months. Over the course of the study, three people were lost to follow-up in the TRAK-ACL arm and eight were lost to follow-up in TAU (table 3).

Completeness of outcome data

The completeness of outcome data suggested that the number, complexity and time taken to complete items were all acceptable to participants, indicating that data collection for a fully powered RCT will be feasible. All but one outcome measure had 100% item completion

Table 4 Outcome and data completeness

	Total	TAU	TRAK-ACL
Outcome completeness	**Freq (%)**	**Freq (%)**	**Freq (%)**
KOOS			
0	51 (100)	25 (100)	26 (100)
3	44 (86.27)	19 (76)	25 (96.15)
6	40 (83.96)	17 (68)	23 (88.46)
No of items	42	42	42
Complete items	42 (100)	42 (100)	42 (100)
Self-efficacy			
0	51 (100)	25 (100)	26 (100)
3	44 (86.27)	19 (76)	25 (96.15)
6	40 (78.43)	17 (68)	23 (88.46)
No of items	6	6	6
Complete items	6 (100)	6 (100)	6 (100)
CSRI			
0	51 (100)	25 (100)	26 (100)
3	44 (86.27)	19 (76)	25 (96.15)
6	40 (78.43)	17 (68)	23 (88.46)
No of items	114	114	114
Complete items	64 (54.38)	79 (69.29)	102 (89.47)
WPAI			
0	51 (100)	25 (100)	26 (100)
3	44 (86.27)	19 (76)	25 (96.15)
6	40 (78.43)	17 (68)	23 (31.08)
No of items	6	6	6
Complete items	6 (100)	6 (100)	6 (100)
EQ-5D-5L			
0	51 (100)	25 (100)	26 (100)
3	44 (86.27)	19 (76)	25 (96.15)
6	40 (78.43)	17 (68)	23 (31.08)
No of items	5	5	5
Complete items	5 (100)	5 (100)	5 (100)

Strength outcome	**3 months**	**6 months**
Leg extension		
Total in study at site 1	37	33
Yes	33 (89.18)	30 (90.90)
No	4 (10.81)	3 (9.09)
Reason	Pain or DNA	Pain or DNA

Physiotherapy appointments	**n=51, mean (SD)**
Total physiotherapy appointments per person	16.01 (5.04)

EQ-5D-5L, an instrument for measuring generic health related quality of life
CSRI, Client Services Receipt Inventory; KOOS, Knee Injury and Osteoarthritis Outcome Score; TAU, treatment as usual; TRAK—ACL, taxonomy for the rehabilitation of knee conditions—ACL; WPAI, work productivity and impairment.

for each outcome (table 4). The CSRI was the exception in that it was only completed by 54% of participants at baseline, and then 69% and 89% at 3 and 6 months.

TRAK-ACL usage data

Usage of the TRAK-ACL intervention was measured by the number of logins to the website, videos watched and behaviour change functions used, for example, exercise log, goal setting or weekly progress. These findings are displayed in full detail in online supplemental information 2—TRAK-ACL usage data. In summary, the median number of logins per patient participant was 5 with IQR of 3–13. The median (IQR) patient logins per week was 4 (2–7). The time between patients' first and last login was a mean of 18 weeks (12.2SD), which suggests that users continue to engage over time and across phases of care. The median (range) physiotherapist logins

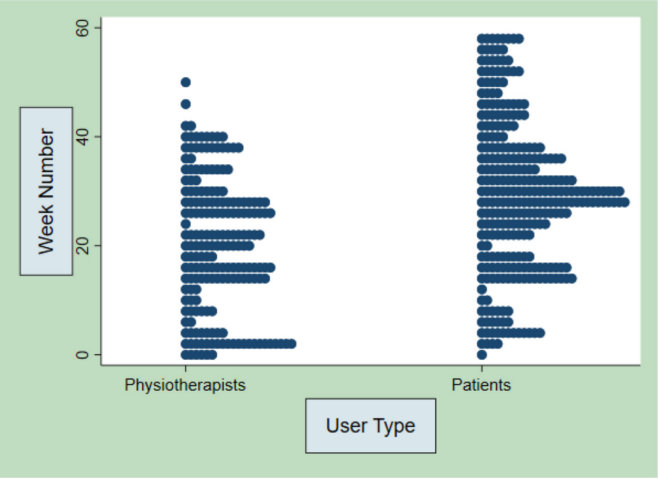


Figure 2 Physiotherapist and patient logins over 60-week duration of the feasibility trial.

per week was 2 (0–5). The median (range) logins per physiotherapist over the duration of the trial was 11.5 (6–18.5). The logins of physiotherapists and patients over 60 weeks, given in figure 2, showed consistency of patient usage as physiotherapist usage dwindles and disappears over the last 20 weeks.

There were no reported adverse events for participants enrolled on this feasibility trial.

Analysis of secondary outcomes

The analysis of secondary outcomes is discussed in online supplemental information 3. The results show that the primary outcome of a future substantive RCT would be the KOOS at 6 months follow-up. A power calculation assuming a SD of 17.2671 on the KOOS estimates that a sample size of 172 participants (86 per study arm) will be required to detect a nine point difference on the KOOS between intervention and control groups with 90% power and 5% alpha. After inflation for 20% loss to follow-up, this figure increases to 108 participants per arm, 216 in total.

DISCUSSION

Principal findings

The aim of the study was to determine the feasibility of an RCT comparing TRAK-ACL plus TAU to TAU in the management of postoperative patients with ACL. The findings suggest a future RCT to determine effectiveness, as measured by the KOOS, would be feasible, as patients were successfully recruited and retained and provided adequate outcome data, with the exception of the CSRI. Further work may be needed to improve data collection for an assessment of cost-effectiveness. The findings on usage suggest that patients and physiotherapists engaged with the TRAK-ACL intervention, in terms of number of log-ins, uptake of material and duration of engagement.

Recruitment and retention

Eighty-six per cent of those approached about the study were recruited. The recruitment target of four patients per month was exceeded at site 1 where there was a dedicated researcher to facilitate recruitment. Site 2 recruitment was affected by changes to orthopaedic team leading to a significant drop in patients with ACL reconstruction. This could have been anticipated by better engagement with orthopaedics through the planning stage. It is known that recruitment challenges can be a key reason why randomised trials fail[32] so a robust recruitment outcome was important.[33] Recruitment method was highlighted as a key barrier to participation in previous DHI studies where in one example less than half of the physiotherapists allocated to delivering DHI actually recruited patients[34] and in another only 30% of eligible patients were recruited.[35] Strategies such as personalising the intervention (personal exercise plans) and dedicated staff support were implemented in the current study which may have contributed to recruitment success.[36]

At 6-month follow-up 78% of participants were retained, which exceed the criteria set for this study of less than 30% drop-outs. Eysenbach *et al* described two types of attrition; non-usage attrition (non-use of the DHI) and drop out attrition (lost to follow-up in the trial).[37] Some patient loss can be explained by typical drop out from physiotherapy over the duration of ACL rehabilitation,[38] and dropout rates can exceed 30% in trials for DHI and exercise.[14 39] This study suggests that patients with ACL reconstruction will engage with the DHI and trial process over time and that the role of the research assistant seems key to facilitating outcome collection.

Usage of TRAK-ACL

Usage data from TRAK-ACL show that there was consistent engagement by some users over time, indicating improved access to care. For the current study, a progression criterion of three logins per week per patient was set based on current evidence.[4] Use of the behaviour change mechanisms such as logs, goal setting and educational and motivational content was accessed by up to 50% of patient TRAK-ACL users which may have improved these patients adherence to the target behaviour.

The usage data shown in this trial are similar to reported use data for health websites and apps used alongside treatment as usual.[35 40–42] Additionally, levels of usage found in this study are similar to those found for other physiotherapy digital intervention feasibility studies[14 43] and may indicate a growing acceptability of DHIs. A future trial would benefit from addressing physiotherapist engagement which may be affected by factors such as time and willingness to adopt new technology, understanding of new technology, the extent to which new technology meets user needs and the workplace support to maximise the potential of new technology.[34 44]

Outcomes

The gathering of clinical outcomes such as KOOS, the self-efficacy score, EQ-5D-5L and work productivity and impairment was also shown to be feasible in this trial. There was 100% completion by all patients who

were retained to the trial at 6 months in four out of five outcomes, which exceeded the feasibility progression criterion of 80% completion set for this study. The exception to good outcome collection was the CSRI. It is considered a valuable tool of health economic analysis and should be included where possible.[45 46] In a future RCT, a digital rather than paper version could facilitate cleaner more usable data. Likewise, strength testing would be a key outcome of a future trial.[3 47] The method of collecting strength testing across sites was not standardised and in a future trial isokinetic muscle strength testing of quadriceps and hamstrings at 180°/s should be considered. Feasibility of strength testing was successful however, clinical trial standard strength testing requires standardised conditions and calibration of machines.[48]

Strengths and limitations

The strength of this study was the success of recruitment pathways, outcome measures and intervention toward determining feasibility. Progression to a full RCT would be recommended as the feasibility progression criteria for recruitment, retention, completeness of outcome measures at 6 months and adverse outcomes have all been met. The total sample size calculated for a full RCT was 216 participants (allowing for drop-outs). This would be achievable based on the recruitment to this study but would require 12 months' recruitment over a minimum of five sites.

Not all patient participants engaged with all aspects of the behaviour change mechanisms built into TRAK-ACL and physiotherapists did not appear to sustain engagement with TRAK-ACL through to the return to sport phase of rehabilitation. Exploring this in a qualitative study would have strengthened this study and design of a future RCT. Measuring the number of face-to-face physiotherapist contacts would help evaluate if TRAK-ACL resulted in reduced physiotherapist contacts. The study was limited by the specificity of usage measurement that TRAK-ACL was capable of when considered against the AMUsED framework, a standard for reporting usage in digital trials.[49] In a future trial, TRAK-ACL would need more specific usage measurement capabilities.

CONCLUSIONS

The results of this study suggest that TRAK-ACL is suitable to go forward to a fully powered RCT investigating whether patients using a DHI as well as treatment as usual have better outcomes than patients receiving just treatment as usual. It is essential that sufficient support for trial delivery is built into a future RCT. Future research should aim to ensure that the DHI is stable and capable of measuring all relevant aspects of engagement before going to trial.

New findings

Patient engagement with educational resources and exercises on the DHI occurs across multiple phases of the rehabilitation.

Digital health tools such as the TRAK-ACL website may provide an opportunity to teach and reinforce the key lessons and exercises at each stage of rehabilitation, as well as engage patients through behaviour change functions.

DHI may be crucial for patients who do not have access to physiotherapy throughout rehabilitation.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not required.

Ethics approval Ethical approval was obtained (18/LO/0403). The trial was registered with the ISRCTN (ID ISRCTN55635910) and the NIHR Clinical Research Network Portfolio: CPMS ID 37879.

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Data availability statement Deidentified participant data are available upon reasonable request.

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REFERENCES

1 Hewett TE, Ford KR, Hoogenboom BJ. *Understanding and preventing ACL injuries: current biomechanical and epidemiologic considerations*. . North American journal of sports physical therapy : NAJSPT, 2010: 5. 234–51.
2 Bollen S. Epidemiology of knee injuries: diagnosis and triage. *Br J Sports Med* 2000;34:227–8 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1763268/pdf/v034p00227a.pdf
3 Grindem H, Snyder-Mackler L, Moksnes H, *et al*. Simple decision rules can reduce reinjury risk by 84% after ACL reconstruction: the Delaware-Oslo ACL cohort study. *Br J Sports Med* 2016;50:804–8.
4 Dunphy E, Hamilton FL, Button K, *et al*. A scoping review of the resources needed to deliver anterior cruciate ligament physiotherapy rehabilitation in randomised controlled trials. *Phys Ther Rev [Internet]* 2020;25:81–95 https://www.tandfonline.com/doi/full/
5 A H, Dixon J. The NHS long term plan. *Br Med J Publ Gr* 2019;364:l84.

6 Walker A, Hing W, Lorimer A. The influence, barriers to and facilitators of anterior cruciate ligament rehabilitation adherence and participation: a scoping review. *Sports Med Open* 2020;6:32.
7 Edwards PK, Ebert JR, Joss B, *et al*. Patient characteristics and predictors of return to sport at 12 months after anterior cruciate ligament reconstruction: the importance of patient age and postoperative rehabilitation. *Orthop J Sports Med* 2018;6:2325967118797575.
8 Bailey DL, Holden MA, Foster NE, *et al*. Defining adherence to therapeutic exercise for musculoskeletal pain: a systematic review. *Br J Sports Med* 2020;54:326–31.
9 NHS Digital. *Digital inclusion for health and social care*, 2019.
10 Spasić I, Button K, Divoli A, *et al*. TRAK APP suite: a web-based intervention for delivering standard care for the rehabilitation of knee conditions. *JMIR Res Protoc* 2015;4:e122 http://www.researchprotocols.org/2015/4/e122/
11 Button K, van Deursen RW, Soldatova L, *et al*. TRAK ontology: defining standard care for the rehabilitation of knee conditions. *J Biomed Inform* 2013;46:615-25.
12 Michie S, van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. *Implement Sci* 2011;6:42.
13 Dunphy E, Hamilton FL, Spasić I, *et al*. Acceptability of a digital health intervention alongside physiotherapy to support patients following anterior cruciate ligament reconstruction. *BMC Musculoskelet Disord* 2017;18:471.
14 Button K, Nicholas K, Busse M, *et al*. Integrating self-management support for knee injuries into routine clinical practice: TRAK intervention design and delivery. *Musculoskelet Sci Pract* 2018;33:53-60.
15 Craig P, Dieppe P, Macintyre S, *et al*. Developing and evaluating complex interventions: the new medical Research Council guidance. *BMJ* 2008;337:a1655 http://www.bmj.com/content/337/bmj.a1655
16 Research NI for H. *Definition of feasibility versus pilot studies*, 2019.
17 Eldridge SM, Chan CL, Campbell MJ, *et al*. CONSORT 2010 statement: extension to randomised pilot and feasibility trials. *BMJ* 2016;355:i5239.
18 Dunphy E, Hamilton FL, Button K. Taxonomy for the rehabilitation of knee conditions (TRAK), a digital intervention to support the self-care components of anterior cruciate ligament rehabilitation: protocol of a feasibility study. *JMIR Res Protoc* 2016;5:e234 http://www.researchprotocols.org/2016/4/e234/
19 Julious SA. Sample size of 12 per group rule of thumb for a pilot study. *Pharm Stat* 2005;4:287–91.
20 Billingham SAM, Whitehead AL, Julious SA. An audit of sample sizes for pilot and feasibility trials being undertaken in the United Kingdom registered in the United Kingdom clinical research network database. *BMC Med Res Methodol* 2013;13:104.
21 Sim J, Lewis M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J Clin Epidemiol* 2012;65:301–8.
22 Whitehead AL, Sully BGO, Campbell MJ. Pilot and feasibility studies: is there a difference from each other and from a randomised controlled trial? *Contemp Clin Trials* 2014;38:130–3.
23 Frobell RB, Roos EM, Roos HP, *et al*. A randomized trial of treatment for acute anterior cruciate ligament tears. *N Engl J Med* 2010;363:331–42.
24 Risberg MA, Holm I, Myklebust G, *et al*. Neuromuscular training versus strength training during first 6 months after anterior cruciate ligament reconstruction: a randomized clinical trial. *Phys Ther* 2007;87:737–50.
25 Hoffmann TC, Glasziou PP, Boutron I, *et al*. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014;348:g1687.
26 Blatch-Jones AJ, Pek W, Kirkpatrick E, *et al*. Role of feasibility and pilot studies in randomised controlled trials: a cross-sectional study. *BMJ Open* 2018;8:e022233.
27 Roos EM, Roos HP, Lohmander LS, *et al*. Knee Injury and Osteoarthritis Outcome Score (KOOS)--development of a self-administered outcome measure. *J Orthop Sports Phys Ther* 1998;28:88–96. doi:10.2519/jospt.1998.28.2.88
28 Lorig KR, Sobel DS, Ritter PL, *et al*. Effect of a self-management program on patients with chronic disease. *Eff Clin Pract* 2001;4:256–62 http://www.ncbi.nlm.nih.gov/pubmed/11769298
29 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of Life Research* 2011;20:1727–36.
30 Roos EM, Lohmander LS. The knee injury and osteoarthritis outcome score (KOOS): from joint injury to osteoarthritis. *Health Qual Life Outcomes* 2003;1:64.
31 Hollis S, Campbell F. What is meant by intention to treat analysis? survey of published randomised controlled trials. *BMJ* 1999;319:670–4.
32 Briel M, Olu KK, von Elm E, *et al*. A systematic review of discontinued trials suggested that most reasons for recruitment failure were preventable. *J Clin Epidemiol* 2016;80:8–15.
33 Bower P, Brueton V, Gamble C, *et al*. Interventions to improve recruitment and retention in clinical trials: a survey and workshop to assess current practice and future priorities. *Trials* 2014;15:399.
34 Kloek CJJ, Bossen D, de Vries HJ, *et al*. Physiotherapists' experiences with a blended osteoarthritis intervention: a mixed methods study. *Physiother Theory Pract* 2020;36:572–9.
35 Goode K. *Evaluation of a digital health resource providing physiotherapy information for postnatal women in a tertiary public hospital in Australia*. . mHealth, 2018: 4. 42.
36 O'Connor S, Hanlon P, O'Donnell CA, *et al*. Understanding factors affecting patient and public engagement and recruitment to digital health interventions: a systematic review of qualitative studies. *BMC Med Inform Decis Mak* 2016;16:120.
37 Eysenbach G. The law of attrition. *J Med Internet Res* 2005;7:e11.
38 Hartigan EH, Axe MJ, Snyder-Mackler L. Time line for noncopers to pass return-to-sports criteria after anterior cruciate ligament reconstruction. *J Orthop Sports Phys Ther* 2010;40:141–54.
39 Levinger P, Dunn J, Bifera N, *et al*. High-speed resistance training and balance training for people with knee osteoarthritis to reduce falls risk: study protocol for a pilot randomized controlled trial. *Trials* 2017;18:384 http://ovidsp.ovid.com/ovidweb.cgi?T=JS&PAGE=reference&D=med14&NEWS=N&AN=28821271
40 Kristjánsdóttir OB, Fors EA, Eide E, *et al*. A smartphone-based intervention with diaries and therapist-feedback to reduce catastrophizing and increase functioning in women with chronic widespread pain: randomized controlled trial. *J Med Internet Res* 2013;15:e5.
41 Matthews L, Pugmire J, Moore L, *et al*. Study protocol for the 'HelpMeDoIt!' randomised controlled feasibility trial: an app, web and social support-based weight loss intervention for adults with obesity. *BMJ Open* 2017;7:e017159.
42 Murray E, Sweeting M, Dack C, *et al*. Web-based self-management support for people with type 2 diabetes (HeLP-Diabetes): randomised controlled trial in English primary care. *BMJ Open* 2017;7:e016009.
43 Lowe CJM, Kelly P, Milton K, *et al*. WALK30X5": a feasibility study of a physiotherapy walking programme for people with mild to moderate musculoskeletal conditions. *Physiother* 2020;107:275–85.
44 Topol E. *The Topol review. preparing the healthcare workforce to deliver the digital future*, 2019.
45 Jessep SA, Walsh NE, Ratcliffe J, *et al*. Long-term clinical benefits and costs of an integrated rehabilitation programme compared with outpatient physiotherapy for chronic knee pain. *Physiotherapy* 2009;95)::94–102. Jun;.
46 Knapp M, Chisholm D. *Client socio-demographic and service receipt inventory–European version*, 2006.
47 Lynch AD, Logerstedt DS, Grindem H, *et al*. Consensus criteria for defining 'successful outcome' after ACL injury and reconstruction: a Delaware-Oslo ACL cohort investigation. *Br J Sports Med* 2015;49:335–42.
48 Winter EM, Jones AM, Davison RR, *et al*. *Sport and exercise physiology testing guidelines: volume I–Sport testing: the British association of sport and exercise sciences guide*. Routledge, 2006.
49 Miller S, Ainsworth B, Yardley L, *et al*. A framework for analyzing and measuring usage and engagement data (AMUsED) in digital interventions: viewpoint. *J Med Internet Res* 2019;21:e10966 http://www.jmir.org/2019/2/e10966/

Supplementary Information 1 - The TRAK Website and Treatment as Usual

The Intervention

All participants received Treatment as Usual (TAU), which was delivered face-to-face and those in the intervention arm also received the TRAK-ACL website. TRAK-ACL has 3 views, one for participants, one for physiotherapists and a third administrator view.

TRAK-ACL website

TRAK-ACL is an evidence based website specifically designed to support patients after ACL reconstruction. It reinforces the teaching and exercise prescription given in usual physiotherapy care. The website includes an extensive phase by phase (early, middle, advanced and return to sport) video exercise library. Physiotherapists can prescribe groups of exercises for their patients or guide them to work independently in a particular phase. It also includes a phase by phase library of evidence based information that is provided as animations, infographs, text and expert videos, to facilitate learning at each stage of care. Video participants included PPI participants and orthopaedic and physiotherapy colleagues who participated in the study. The website was developed in line with the Behaviour Change Wheel framework for intervention design(1) and it incorporated features such as educational materials, personal goal setting, progress logs and dashboards of progress which are associated with theories of behaviour change and can promote engagement with rehabilitation behaviours.

TRAK training for staff

A two hour training event was provided at each site. It included the functionality of the TRAK-ACL website, the research process and the integration with current care. Training content was decided based on prior TRAK studies and feedback from previous users (2, 3).

Physiotherapist participants were informed about the research objectives, and the concepts of supported self-management and behaviour change that underpin the functions of TRAK-ACL. Each physiotherapist was taught to set up and manage a patient user and how to teach the patient to access and utilise the key functions of TRAK (Figure 1).

Further support was available through laminated guidance sheets that were on hand in the rehabilitation area to remind clinicians of the key points. Each physiotherapist participant had a summary of instructions emailed to them and further sessions of TRAK-ACL training were offered ad hoc for new starters or for anyone who requested support.

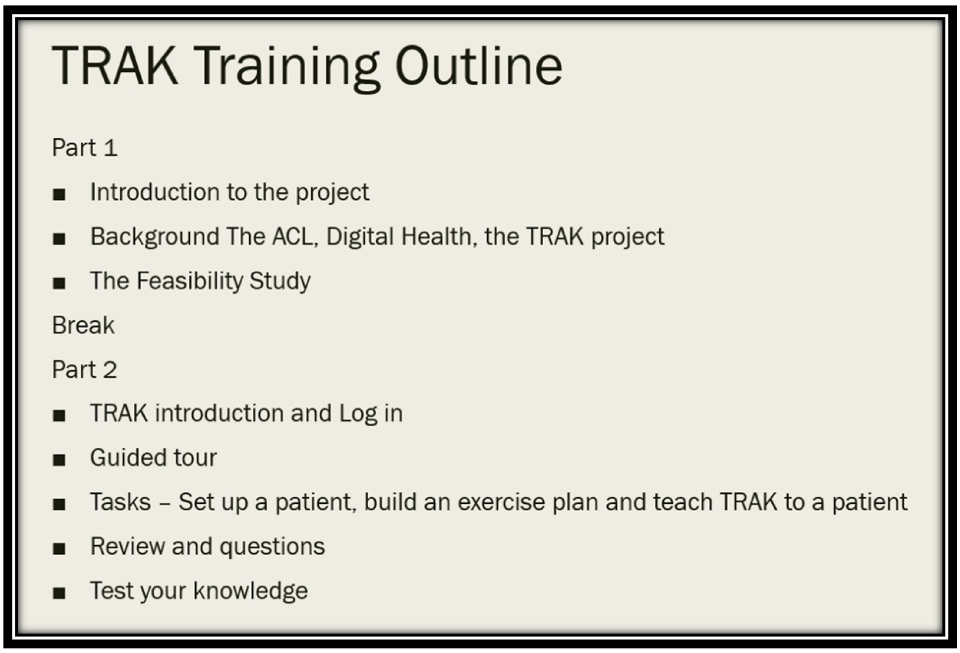

Figure 1. Contents of TRAK training

The results of a previous TRAK-ACL Acceptability study highlighted the need to make TRAK-ACL quicker for physiotherapists to use such as the inclusion of grouped exercise 'playlists' (2). Use of playlists were also included in training to facilitate a smoother integration of TRAK-ACL into usual clinical interactions. Figure 2 shows the functions where exercises could be selected as a group to save time, which we referred to as playlists, but the developer referred to as 'prescribe default exercises'. A further results of the previous study highlighted the need for efficient Wi-Fi and fast working tablets to use in a rehabilitation gym environment. The WiFi was checked at all sites and a MiFi (personal modem) was provided in one gym that did not have a good signal. Apple iPads were also provided, 2 at each site.

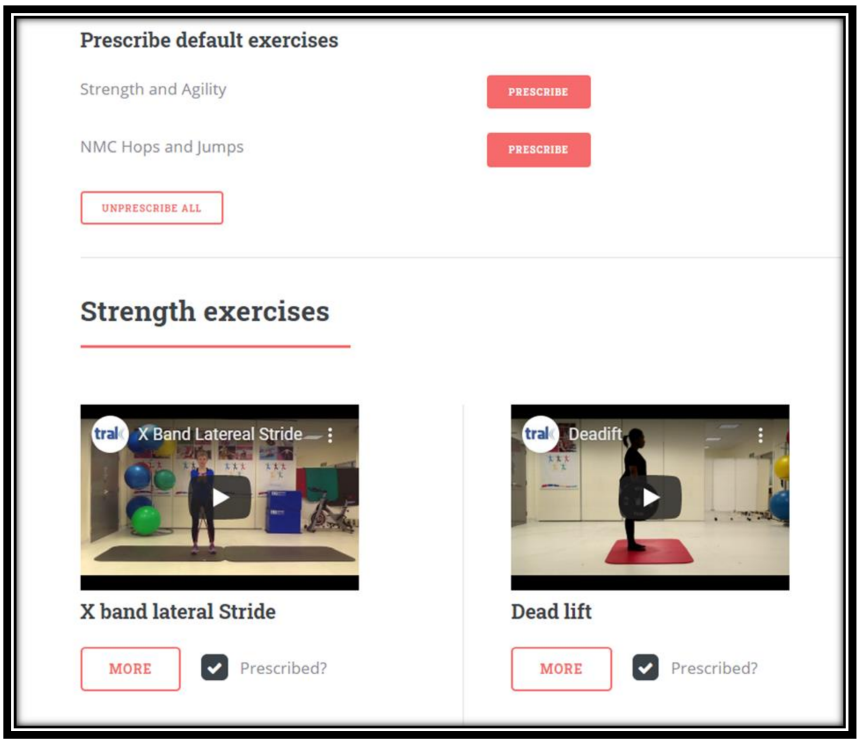

Figure 2. Playlists / 'Prescribe default exercises'

Patient Participant Intervention Training

Each patient in the intervention arm had a TRAK-ACL induction that was delivered by the treating physiotherapist. They were assigned an alphanumeric log in, which was a combination of their site location and the first four numbers of their birthdate. The password for all patients was set as 'patient'. Patients were guided to set goals, record progress and follow exercise plans as directed by their physiotherapist. Patients were invited to seek further TRAK-ACL support from their physiotherapist as needed.

Treatment as usual

Treatment as usual for ACL rehabilitation was given to all study participants in both groups. The control group had treatment as usual only. Initial referral to physiotherapy always came from the orthopaedic department following ACL reconstruction. Following this the treatments varied by site.

Treatment as usual at Site 1

Patients were seen in an ACL group environment with separate classes for each phase. Care continued until rehabilitation goals were met and this could vary between individuals depending on

their goals but was usually from 6-12 months. Classes were one hour long. Initially they were weekly and they progressed to fortnightly once the patient achieved a set of criteria (usually between 12 and 16 weeks). Patient progression was based on meeting established criteria rather than time (4). They could choose to do a final return to sport phase depending on their personal goals. Attendance for this phase could be fortnightly or monthly depending on need.

Different time slots and classes accommodated the different phases of care and in each class the objectives of that phase were reinforced to the patients. Classes were well staffed so that individual assessment, problem solving, exercise prescription and management could occur.

Treatment as usual at Site 2

Treatment as usual at Site 2 had the same structure as Site 1. There were weekly dedicated ACL rehabilitation classes where patients progressed through phases of care. Unlike Site 1, Site 2 care was split across several sites.

Treatment as usual at Site 3.

At Site 3, patients were referred to the physiotherapy service and given an urgent post-operative priority. They had one-to-one physiotherapy at one of several sites across the catchment area. The initial appointment was 45 minutes and follow-up appointments were for 30 minutes. Induction was personalised but aimed to include reassurance, education, setting expectations, wound check, baseline outcomes and exercise education. Appointment frequency was determined by service capacity and needs of the patient based on physiotherapist assessment. When patients achieved an agreed criteria they could join a generalised lower limb rehabilitation class for 6 weeks, which was 1 hour long. They were reviewed in one-to-one care after this and had the option of being referred to a generalised advanced lower limb class which was held on a weekly basis. Continued attendance at the class was re-assessed after 6 weeks. Those who were unable to attend the exercise class continued to be managed on a one to one basis. The duration of treatment was based on patient need and there was no restriction on the duration of treatment.

References

1. Michie S, Van Stralen MM, West R. The behaviour change wheel: a new method for characterising and designing behaviour change interventions. Implementation science. 2011;6(1):42.
2. Dunphy E, Hamilton FL, Spasić I, Button K. Acceptability of a digital health intervention alongside physiotherapy to support patients following anterior cruciate ligament reconstruction. BMC musculoskeletal disorders. 2017;18(1):471.

3. Button K, Nicholas K, Busse M, Collins M, Spasić I. Integrating self-management support for knee injuries into routine clinical practice: TRAK intervention design and delivery. Musculoskeletal Science and Practice. 2018;33:53-60.
4. van Melick N, van Cingel RE, Brooijmans F, Neeter C, van Tienen T, Hullegie W, et al. Evidence-based clinical practice update: practice guidelines for anterior cruciate ligament rehabilitation based on a systematic review and multidisciplinary consensus. British journal of sports medicine. 2016;50(24):1506-15.

Supplementary Information 2 – **TRAK-ACL usage Data**

This supplementary information presents the TRAK-ACL usage data that was collected to measure engagement with the various functions of TRAK-ACL.

Logins

Patient participants

There were a total of 279 patient logins over the 63 weeks of the study. There were 22 participants in total with one participant accounting for 113 logins. The median (interquartile range, IQR) number of logins from all patient participants per week was 4 (2-7). The median number of logins per participant was 5 IQR 3 – 13). The mean (Standard Deviation, SD) time elapsed between patients first and last log in was 18 (SD 12.2) weeks (Table 1). This suggests that patient users engaged with TRAK-ACL over time and different phases of care. The actual usage may be higher than reflected by the total number of logins as, unfortunately, logins were not timed out automatically and therefore patients could remain logged in over weeks and could use many TRAK-ACL features leaving no imprint.

Physiotherapists

Eight physiotherapists logged in 108 times over the trial. The median (range) physiotherapist logins per week was 2 (0-5) (Table 2). The median (range) logins per physiotherapist over the duration of the trial was 11.5 (6-18.5). The mean (SD) number of weeks of use was 28.8 (18.4). Figure 1 shows patient and physiotherapist logins over 20 weeks with the activity of the one patient 'superuser' separated out from other patient logins.

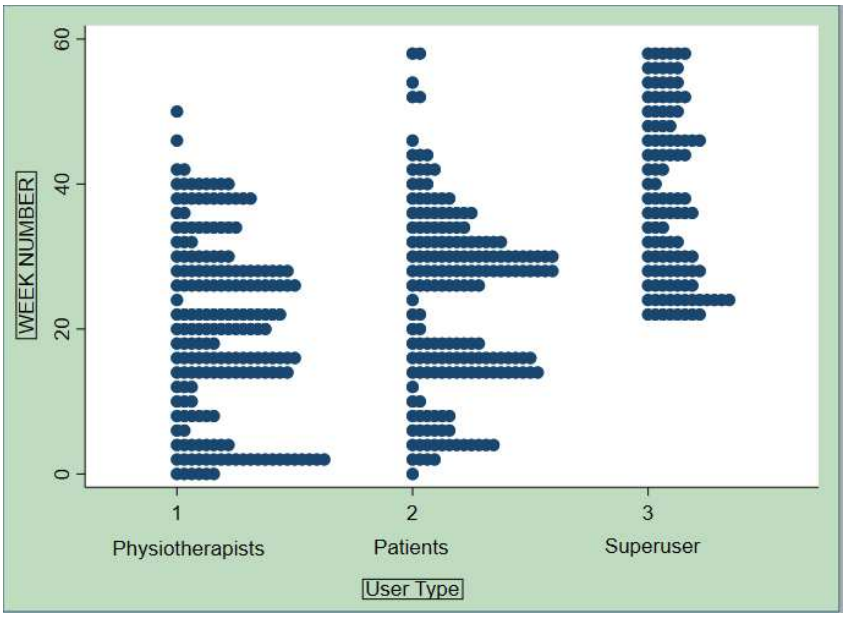

Figure 1. Physiotherapist and patient logins with 'superuser' separated over 20 week duration of the feasibility trial

Prescribed exercises

There were a total of 776 prescribed exercises. There was a median (IQR) of 34 (27-51) exercises prescribed per patient. The most commonly prescribed type of exercise was strength exercise with a total of 396 (51.03) strength exercises prescribed. Otherwise the exercise types were spread across a range of physical rehabilitation categories outlined in Table 1. The prescription of exercises was spread across the stages of care. Phase 1: Early Physiotherapy had 320 (41.24%). Phase 2: Intermediate Physiotherapy had slightly more at 373 (48.07%) while Phase 3: Advanced Physiotherapy had 83 (10.70%). There were no exercises prescribed in the Phase 4: Return to Sport Physiotherapy

TRAK Usage	
Logins	**Freq (%)**
Physiotherapist n=8	108 (27.90)
Patient n=22	279 (72.09)
	Median (IQR)
Logins per patient n=22	5 (2.0-17.0)
Logins per physiotherapist n=8	11.5 (6.0-18.5)
Logins p/week: Patient	4 (2.0-7.0)
Logins p/week : Physiotherapist	2 (0.0-5.0)
	Mean (SD)
Weeks of use (first to last log in) patients	18 (12.2)
Weeks of physiotherapist use	28.8 (18.4)
Prescribed Exercises	Median (IQR)
Prescribed exercises per patient	34 (27.0-51.0)
Prescribed exercises per physiotherapist (n=5)	163 (29.0-195.0)
Prescribed exercises per physio per week (n=5)	23.2 (15.0)
Types of exercise prescribed	**Freq (%)**
Total	776 (100)
Agility	37 (4.77)
Cardiovascular	13 (1.68)
Flexibility	108 (13.92)
Hops and Jumps	70 (9.02)
Neuromuscular Control	122 (15.72)
Run drills	8 (1.03)
Strength	396 (51.03)
Trunk Strength	22 (2.84)
Exercise Phase	**Freq (%)**
Phase 1: Early Physiotherapy	320 (41.24)
Phase 2: Intermediate Physiotherapy	373 (48.07)
Phase 3: Advanced Physiotherapy	83(10.70)
Phase 4: Return to Sport Physiotherapy	0

Table 1. Logins and Prescribed exercises

Behaviour change techniques	Median (IQR) n=22	Number of individual users	Number of uses	Spread
Goal Setting	1 (0-3)	11 users	43 Goals (n=11)	1-11 (n=11)
Weeks over which goals were used	4(4-8)			
Weekly Log	0 (0-1)	10 users	124 logs	1-71(n=10)
Weeks over which weekly log used	4 (4-12)			

Exercise Log	0 (0-16)	8 users	989 logs	3-713 (n=8)
Weeks over which exercise logs used	14 (8-20)			

Table 2. Behaviour Change Functions

Behaviour change functions

Table 2 described patients' use of behaviour change functions. There were 22 users of which 11 entered personal goals. These 11 entered a total of 43 goals, with a range of 1 – 11 goals per user. Of the 22 users, the median number of goals per user was 1 (IQR 0 – 3). Ten users utilized the weekly log function. They created 124 weekly logs with a spread of 1-71 logs per patient. The median weekly logs was 0 (0-1) n=22. The detailed exercise log had 8 users who entered 989 logs with a range of 3-713, and the median was 0 (IQR 0-16) n=22. This engagement of the 'superuser' appears to be responsible for the skew in results.

Educational videos and animations

TRAK itself was unable to measure videos clicked by user so the analysis of video usage was limited to YouTube's built in analytics. This allows views to be broken down into 'external' view sources which means sources other than a YouTube search, ie a link or implanted video on another website. Within these 'external sources', we could isolate the views that came directly from the TRAK-ACL website since they were labelled with the TRAK-ACL website server details. These videos are not available anywhere except TRAK-ACL so we can be sure that only study participants accessed these videos. Results are shown in Table 3.

The data is presented as number of views, average duration viewed as compared with total duration and percentage of overall video watched. The Phase 1 Animation was viewed 11 times (73% viewed). The Phase 2 Animation was viewed 11 times (82%). The Phase 3 Animation was viewed 7 times (87%) and the Phase 4 animation was viewed 6 times (78%). The Psychological factors of ACL rehabilitation animation was viewed 6 times (78%). These figures indicated an overall good uptake of educational material.

The expert videos proved less popular than the animations. The orthopedic surgeon expert video was viewed 7 times, for an average of 1 minute and 4 seconds (41%). The physiotherapist expert phase by phase videos were an alternative to the animations but with the same content. These were viewed less often, with the Phase 1 video viewed 4 times (59%). The Phase 2 video was viewed 2 times (12%), the Phase 3 video was not viewed at all. The Phase 4 video was viewed once for 21 seconds (8%). An expert video alternative to the psychological factors video was not viewed at all. A video demonstrating 'Good and Bad Knee Control' was viewed twice (100%). The combined uptake

of these videos and animations was good, however, since we cannot match them to individual users, we are unable to assess how many individual participants engaged with this educational material.

Educational Videos	Views	Average View Duration	Total Duration	% of total viewed
Orthopaedic Surgeon Video	7	00:01:04	4:02	26%
Phase 1 Animation	11	00:01:31	2:05	73%
Phase 2 Animation	11	00:02:20	2:50	82%
Phase 3 Animation	7	00:02:14	2:34	87%
Phase 4 Animation	6	00:02:10	2:46	78%
Psychological Factors Animation	6	00:01:59	2:32	78%
Expert Videos	**Views**	**Average View Duration**	**Total Duration**	**% of total viewed**
Expert video Overview of ACL rehabilitation	4	00:01:02	2:32	41%
Phase 1 Expert Video	4	00:01:26	2:26	59%
Phase 2 Expert Video	2	00:00:24	3:14	12%
Phase 3 Expert Video	0	0	4:15	0%
Phase 4 Expert Video	1	00:00:21	4:20	8%
Psychological Expert Video	0	0	4:14	0%
Good Control Bad Control	2	00:00:38	00:38	100%

Table 3. Educational videos and animations

Supplementary information 3 - Analysis of secondary outcomes

KOOS

Each of the subscales of KOOS was analysed separately. KOOS Pain scores are shown in Table 1 for time point 0, 3 and 6 months. When comparing the two groups, TRAK-ACL and TAU, the intervention effect is measured by the p-value and 95% confidence intervals (95% CI). The mean difference in the intervention effect from baseline to 3 months for Pain was 3.97 (95% CI -1.803 to 9.756), p= 0.172 and 1.09 (-6.609 to 8.799), p=0.775, for baseline to 6 months. For KOOS Symptoms (Table 2) the intervention effect difference from baseline to 3 months was 1.49 (-5.603 to 8.596), p=0.673 and -6.70 (-17.096 to 3.687), p=0.199, for baseline to 6 months. For KOOS activities of daily living (ADL) the intervention effect difference between baseline to 3 months was 2.54 (-1.936 to 7.018), p=0.258 and 2.08 (-1.061 to 5.222), p=.188 for baseline to 6 months. For KOOS sport and recreation (SportRec) the intervention effect difference between baseline and 3 months was 7.8 (-6.51 to 22.111), p=0.278 and 2.27 (-10.007 to 14.560) ,p=0.71 for baseline to 6 months. Finally, for KOOS quality of life (QOL) the intervention effect difference between 0 and 3 months was 4.94 (-4.060 to 13.948), p=0.274 and -4.10 (-15.900 to 7.685), p=0.485 for 0 to 6 months. The KOOS scores at each time point for the 4 key KOOS domains are shown in Figure x. In all cases no difference was found between TRAK-ACL and TAU.

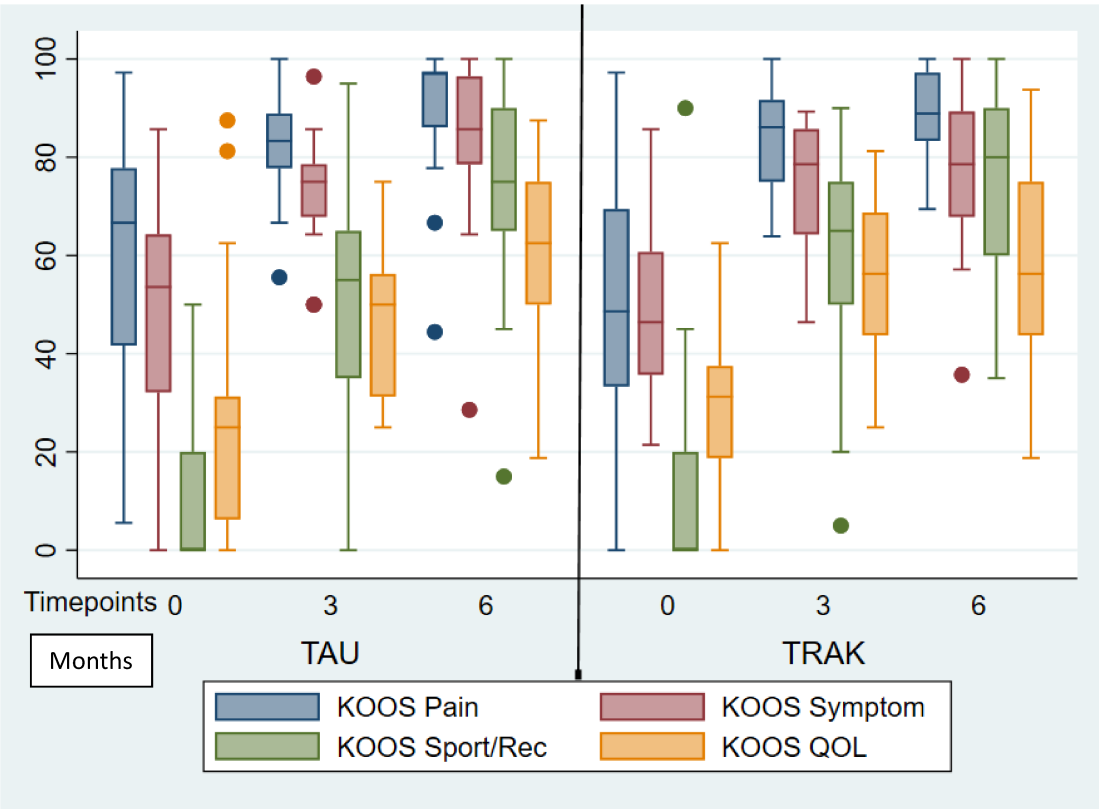

Figure x. Four domains of KOOS at 3 time points for TRAK and TAU.

Legend

TAU = Treatment as usual

TRAK= TRAK-ACL intervention arm

KOOS = Knee Osteoarthritis Outcome Score

QOL= Quality of Life

Outcome	TAU Summary Statistics N= , Mean (SD)	TRAK Summary Statistics N= , Mean (SD)	Intervention Effect Difference of means (95% CI) and p value
KOOS KOOS Pain 0 3 6	 25, 59.11 (24.00) 19, 82.31(10.68) 17, 89.54(14.71)	 26, 51.28 (24.79) 25, 84.22(10.10) 23, 89.37(09.57)	 3.97 (-1.803, to 9.756) p= 0.172 1.09 (-6.609 to 8.799) p=0.775
KOOS Symptoms 0 3 6	 25, 49.71(12.17) 19, 72.93(11.12) 17, 84.03(17.64)	 26, 47.12(17.02) 25, 74.43(11.88) 23, 77.33(14.79)	 1.49 (-5.603 to 8.596) p=0.673 -6.70 (-17.096 to 3.687) p=0.199
KOOS ADL 0 3 6	 25, 64.17(27.00) 19, 91.87(08.06) 17, 95.76(06.13)	 26, 57.35(25.29) 25, 94.17(06.40) 23, 97.44(03.61)	 2.54 (-1.936 to 7.018) p=0.258 2.08 (-1.061 to 5.222) p=0.188
KOOS SportRec 0 3 6	 25, 9.8(14.10) 19, 50 (23.51) 17, 72.94(22.01)	 26, 10.58(20.51) 25, 57.8 (23.14) 23, 75.22(16.41)	 7.80 (-6.51 to 22.111) p=0.278 2.27 (-10.007 to 14.560) p=0.71
KOOS QOL 0 3 6	 25, 25.25(24.70) 19, 47.69(15.48) 17, 61.76(08.99)	 26, 28.37(17.87) 25, 54.75(17.23) 23, 59.23(20.10)	 4.94 (-4.060 to 13.948) p=0.274 -4.10(-15.900 to 7.685) p=0.485
Self-Efficacy Score 0 3 6	 25, 7.27(1.65) 19, 8.30(1.39) 17, 8.50(1.50)	 26, 7.69(1.84) 25, 8.43(1.00) 23, 8.47(1.32)	 .126 (-0.601 to 0.854) p=0.728 -0.03 (-0.949 to 0.871) p= 0.932

Table 1. Exploration of Intervention effect data, KOOS and Self-Efficacy

KOOS: sample size calculation for a future trial

The developers of the instrument recommend that when using the KOOS, a change of 8-10 is considered the minimal clinically important difference and the standard deviation is set to 15 (14, 17, 19, 20).

Domain	Mean	SD
KOOS PAIN Baseline	55.11983	24.48464
KOOS Symptom Baseline	48.38936	20.10576
KOOS ADL Baseline	60.69781	26.11042
KOOS Sport/Rec Baseline	10.19608	17.49173
KOOS QOL Baseline	26.83824	21.33418

Mean KOOS5	= 40.24826	
Mean KOOS4	= 35.13588	
SD KOOS5		= 18.4658
SD KOOS4		= 17.2671

Table x. Means and SD for KOOS at baseline

The SD of 17.2671 from this feasibility trial compares reasonably to similar studies (20) (21) (22) (23). Therefore the primary outcome of a future substantive RCT would be the KOOS at 6 months follow up.

Self-Efficacy Score

The difference in the intervention effect from baseline to 3 months for the Self Efficacy score was .126 (-0.601, 0.854), p=0.728 and -.03 (-0.949 - 0.871), p= .932 for baseline to 6 months.