Document cover sheet

Assessment report: Digital technologies for managing low back pain (addendum)

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		Samuel Harper		
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		Lavinia Ferrante di Ruffano		
		Emma Carr		
		James Scott		
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		Robert Malcolm		
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		Paul Miller		

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		Lavinia Ferrante di Ruffano Emma Carr James Scott Emma Bishop		
4.0	Updates based on company feedback	Heather Davies Robert Malcolm Samuel Harper Paul Miller Lavinia Ferrante di Ruffano Emma Carr James Scott Emma Bishop	12/01/24	12/01/24
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NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

[GID-HTE10021]: Digital Technologies for Managing Low Back Pain

External Assessment Group Report Addendum

Produced by: York Health Economics Consortium (YHEC)

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Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See <u>NICE's Policy on managing interests for board members and</u> employees.

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Responsibly for report

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Abbreviations

Term	Definition	
BIPQ	Brief illness perception questionnaire	
BL	Baseline	
BMI	Body mass index	
CBT	Cognitive behavioral therapy	
CI	Confidence interval	
DHSC	Department of Health and Social Care	
EAG	External assessment group	
FCP	First contact practitioner	
GP	General practitioner	
HCRU	Health care resource utilisation	
ICS	Integrated care system	
IQR	Interquartile range	
LBP	Low back pain	
MAUDE	Manufacturer and User Facility Device Experience	
MHRA	Medicines & Healthcare products Regulatory Agency	
MSK	Musculoskeletal	
MSK-HQ	Musculoskeletal Health Questionnaire	
MTEP	Medical Technologies Evaluation Programme	
NA	Not applicable	
NHS	National Health Service	
NICE	National Institute for Health and Care Excellence	
NICE CG	NICE clinical guideline	
NICE MTG	NICE medical technology guidance	
NICE QS	NICE quality standard	
NPS	Net promoter score	
NRS	Numerical rating scale	
PP	Per protocol	
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses	
PSFS	Patient Specific Functional Scale	
QUORUM	Quality of Reporting of Meta-analyses	
RCT	Randomised controlled trial	
RMDQ	Roland-Morris disability questionnaire	
SD	Standard deviation	

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SE	Standard error
UK	United Kingdom
VAS	Visual analogue scale
Vs	Versus

1 Background of the addendum

The NICE Final Scope for 'GID-HTE10021 Digital Technologies for Managing Low Back Pain' determined 8 technologies should be evaluated as part of the early value assessment. One additional technology (Phio Engage) was identified at a later date of the original assessment and considered relevant for evaluation. 5 of the 9 companies did not submit evidence to NICE, with information in the early value assessment report limited to published evidence identified within the EAG searches (July 2023). During public consultation for the topic, SelfBack ApS and EQL Ltd submitted evidence in confidence for consideration.

Additionally, during public consultation, 4 companies approached NICE with technologies that match the scope of the evaluation, not originally considered as part of the evaluation. The companies of the 4 newly identified technologies were encouraged to submit evidence.

As a result of these developments the EAG has prepared an addendum:

- Summarising the new evidence submitted for SelfBack, Phio Engage and the 4 new technologies, including relevant details for the technologies.
- Documenting a new pragmatic search for published evidence on the 4 new technologies and summarising any relevant evidence identified.
- Discussing the implications of the new evidence on the conclusions raised from the previous report, covering clinical and economic considerations.
- An evidence gap analysis is also provided for each of the companies, in line with the initial EAG report.

2 Overview of the technology

Included in this addendum are digital technologies that provide self-management and/or psychological support for the treatment of non-specific low back pain (LBP) in people aged 16 and over who are eligible for digital technology management. This is described further in the NICE Final Scope and the early value assessment report. Technologies included in the addendum are technologies that have been identified

during the public consultation process, or were included in the original assessment report but have since provided more evidence.

2.1 Included technologies

In total, 6 digital technologies to support the self-management of non-specific LBP are included within this addendum. Details relevant to the early value assessment are summarised in **Error! Reference source not found.**.

Table 2.1: Included technologies

Technology (Company)	Regulatory Status	EAG Summary
Digital Therapist (Sword Health)	The device is registered as a class 1 medical device under UKCA marking. No mention of CE mark. DTAC: Not yet compliant but currently seeking approval.	Target condition: A range of MSK conditions including non-specific LBP. Key features: A personalised end-to-end care delivery programme which comprises initial assessment, triage and treatment. Includes exercise programmes, education and psychosocial interventions such as pain education, cognitive behavioural therapy. NHS staff involvement: Limited involvement as once referred to application, company uses its own team of clinicians. Pathway placement: Can be used at any point in the pathway, including self-referral.
		Safety net to identify specific condition: A physiotherapist conducts an initial clinical assessment that follows Digital Therapist's risk stratification matrix, supported by Al Current use in the NHS:
Flok Health (Flok Health Ltd)	The device is registered as a class 1 medical device under UCKA marking. DTAC: Expected to be confirmed by the end of 2023.	Delivery: Tablet, mobile phone, or computer. Target condition: Non-specific acute, chronic and sub-acute LBP with or without lumbar radiculopathy. Key features: A personalised end-to-end care delivery programme which comprises of initial

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assessment, triage and treatment. Includes exercise programmes, education and psychosocial interventions such as pain education, behavioural coaching and mindfulness-based cognitive therapy.

NHS staff involvement: Limited involvement as once referred to app, company uses their own clinicians. Also has the option of no NHS staff involvement as people can self-refer.

Pathway placement: Can be used at an early stage in pathway due to triage capabilities, including self-referral.

Safety net to identify specific condition: Combination of AI and clinician can be used to identify specific condition.

Current use in the NHS:

Joint Academy (Arthro Therapeutics Ltd) The device is registered as a class 1 medical device under CE marking. No mention of UKCA mark.

DTAC: Not yet applied for DTAC

Delivery: Tablet or mobile phone.

Target condition: Subacute or chronic MSK joint pain.

Key features: Personalised online exercises and sessions guided by physiotherapist. Includes lessons/quizzes and educational content.

NHS staff involvement: Joint Academy physiotherapists provide support to the person through video and via app messaging. They can also discharge, refer and signpost people accordingly. No requirement for NHS staff involvement.

Pathway placement: After triage from a healthcare professional. Application is also set up for the possibility of self-referral.

Safety net to identify specific condition: Individuals are currently referred to the service by a clinician. On sign up to the application, key

questions are asked which may indicate specific conditions. Joint Academy physiotherapist also monitors for specific conditions.

		Current use in the NHS:
Phio Engage (EQL Ltd)	The device is not registered as a medical device under CE or	Delivery: Tablet and mobile phone.
*The technology was previously referred to as: PhioEngage This naming has been updated in the addendum, as clarified in consultation comments.	UKCA marking, as it does not serve any medical functions.	Target condition: MSK disorders or symptoms including non-specific LBP. Key features: Personalised online exercises guided by physiotherapist. Includes online chat functionality, as well as daily and weekly "checkins" where people can contact their clinicians. The current version of Engage (v1.5.7) consists of an updated goal setting and weekly assessment interface to encourage more accurate patient reported outcomes and progress. NHS staff involvement: initial referral from healthcare professional and on-going physiotherapist involvement through prescribing specific exercises, unless EQL clinicians are used. Complimentary digital application (Phio Access) can also be used prior to referral which would reduce NHS time further during triage.
		Pathway placement: Can be used at any point in the pathway, including self-referral.
		Safety net to identify specific condition: MSK clinicians responsible for safety netting, as the application is only used to facilitate care. Complimentary application (Phio Access) can be used prior to Phio Engage to identify clinical concerns.
		Current use in the NHS:
Physitrack (Physitrack)	The device is not registered as a medical device under CE or UKCA marking, as it does not serve any medical functions. Reviewed previously by healthcare regulatory consultancy. DTAC: Compliant	Delivery: Tablet, mobile phone, or computer. Target condition: A range of MSK conditions including non-specific LBP. Key features: Online exercise, education and patient reported outcome measure prescription software.

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		NHS staff involvement: Healthcare practitioners can engage with the person by personalising exercises, education materials and patient reported outcome measures from their Physitrack app account. Pathway placement: Can be used at any point in the pathway. Referred by a clinician.
		Safety net to identify specific condition: No safety net for the app but individuals are referred to the service by a clinician. Current use in the NHS:
SelfBack (SelfBack ApS)	The device is registered as a class 1 medical device under	Delivery: Tablet and mobile phone.
	CE marking. No mention of UKCA mark.	Target condition: Support the management of
*The		back pain, including non-specific LBP.
technology and company were previously referred to as:	DTAC: Not yet compliant but currently seeking approval.	Key features: Supports patient's self-management of non-specific back pain through digital technology which adopts a personalised self-management approach, including exercise programmes.
(SelfBACK		
Consortium) This naming		NHS staff involvement: NHS staff required for the initial triage of patient (using risk stratification tool STarTBack).
has been updated in the addendum, as clarified in consultation		Pathway placement: After initial triage by a GP/FCP. This requires the use of STarTBack risk stratification tool.
comments.		Safety net to identify specific condition: Initial assessment uses STarTBack or similar risk stratification tool alongside clinical judgement. No specific safety netting in the SelfBack application.
		Current use in the NHS:

Key: Al – Artificial intelligence, CBT – Cognitive behavioral therapy, FCP – First contact practitioner, GP – General practitioner, ICS – Integrated care system, LBP – Low back pain, MSK – Musculoskeletal, NHS – National Health Service.

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3 Clinical evidence selection

3.1 Evidence search strategy and study selection

Searches were conducted to identify studies of the named digital technologies listed in **Error! Reference source not found.** to supplement the evidence identified in the previous <u>report</u>. A single set of searches was conducted to identify both clinical and economic evidence. The searches were conducted in a range of resources including published literature, conference abstracts and ongoing research. The searches were conducted in November 2023.

The EAG searches retrieved a total of 158 records after elimination of 44 duplicates. Titles and abstracts were sifted by 1 reviewer (the first 10% assessed by 2 reviewers independently) based on the intervention and population and using the same approach as the main review. A total of 17 full text papers were retrieved and examined by 1 reviewer to select those meeting the scope definition of an eligible technology. Company submissions were received from all 6 companies (EQL Ltd, Flok Health Ltd, Arthro Therapeutics Ltd, Physitrack PLC, SelfBack ApS and Sword Health) and comprised 60 documents which were examined for relevance. 10 of these were relevant records not identified by the EAG searches and were added to full text screening.

Full details of the search methods are provided in Error! Reference source not found.

3.2 Included and excluded studies

A total of 8 relevant records were identified, reporting 5 new unique studies and adding 3 new records to the existing eligible SelfBack randomised controlled trial (RCT) included in the previous review. These are summarised in **Error! Reference source not found.**. All 5 unique studies were identified from the company evidence. Clarification of the study populations was sought for 4 studies evaluating 2 technologies (Phio Engage and SelfBack). The companies (EQL Ltd and SelfBack ApS) confirmed that they included people with non-specific LBP alone.



Table 3.1: Studies selected by the EAG as the evidence base

Design and intervention(s)	Participants and setting	Outcomes	EAG comments			
Phio Engage						
	Design and intervention(s)	Design and intervention(s) Participants and setting	Design and intervention(s) Participants and setting Outcomes Outcomes			

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Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
SelfBack				
Bardal 2023 (Bardal E M et al. 2023) Location: Denmark	Design: Secondary analysis of Sandal 2021 (NCT03798288) (Sandal et al. 2021) GREEN	Participants: SelfBack: 232 confirmed non-specific LBP within previous 8 weeks. Mean age 48.3 (SD 15.0), male 111 (48%), BMI 27.3 (SD 4.7).	RMDQ NRS Pain PSEQ GREEN	Subgroup analysis of patients by age, gender and level of education. Not extracted further (no eligible subgroups).
and Norway	Intervention: SelfBack plus usual care GREEN	Usual care: 229 patients, mean age 46.7 (SD14.4). Male 95 (41%).		

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Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	Comparator: Usual care including advice or treatment offered by clinician. GREEN	Subgroup analysis of patients by age, gender and level of education. AMBER		
		Acute Vs Chronic LBP: Mixed (included LBP of any duration).		
		Setting: Referred (primary practice including GP, physiotherapy, or chiropractic serving as first point of contact; or a specialised outpatient hospital facility). GREEN		
		Place in pathway: After clinical assessment and diagnosis and as addition to usual care. GREEN		
Øverås 2022 (Øverås C K et al.) Location: Denmark	Design: Secondary analysis of an RCT. GREEN Intervention: SelfBack plus usual care. GREEN	Participants: SelfBack: 232 confirmed non-specific LBP within previous 8 weeks. Mean age 48.3 (SD 15.0), male 111 (48%), BMI 27.3 (SD 4.7).	RMDQ EQ-5D Perceived Stress Scale BIPQ PSEQ	Subgroup analysis of patients with multimorbidity or co-occurring MSK pain. Not extracted further (no eligible subgroups).
and Norway	Comparator: Usual care including advice or treatment offered by	Usual care: 229 patients, mean age 46.7 (SD14.4). Male 95 (41%).	Saltin-Grimby Physical Activity Level Scale Patient's Global Perceived Effect	

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Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
	clinician. GREEN	Subgroup analysis of patients with multimorbidity or co-occurring MSK pain. AMBER Acute Vs Chronic LBP: Mixed (included LBP of any duration). Setting: Referred (primary practice including GP, physiotherapy, or chiropractic serving as first point of contact; or a specialised outpatient hospital facility). GREEN Place in pathway: After clinical assessment and diagnosis and as addition to usual care. GREEN	GREEN	
Rughani 2023 (Rughani G et al. 2023) Location : Denmark and Norway	Design: Secondary analysis of an RCT. GREEN Intervention: SelfBack plus usual care. GREEN Comparator: Usual care including advice or treatment offered by clinician. GREEN	Participants: SelfBack: 232 confirmed non-specific LBP within previous 8 weeks. Mean age 48.3 (SD 15.0), male 111 (48%), BMI 27.3 (SD 4.7). Usual care: 229 patients, mean age 46.7 (SD14.4). Male 95 (41%). Subgroup analysis of patients with high levels of depression or stress.	RMDQ PSEQ Global Perceived Effect Patient satisfaction App engagement GREEN	Subgroup analysis of patients with high levels of depression or stress. Not extracted further (no eligible subgroups).

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Study name and location	Design and intervention(s)	Participants and setting	Outcomes	EAG comments
		AMBER		
		Acute Vs Chronic LBP: Mixed (included LBP of any duration).		
		Setting: Referred (primary practice including GP, physiotherapy, or chiropractic serving as first point of contact; or a specialised outpatient hospital facility). GREEN		
		Place in pathway: After clinical assessment and diagnosis and as addition to usual care. GREEN		
Joint Academ	ny			
			_	

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Study name and location	Participants and setting	Outcomes	EAG comments

Key: BIPQ – Brief illness perception questionnaire, BMI – Body-mass index, GP – General practitioner, JA – Joint academy, LBP – Low back pain, MSK – Musculoskeletal, NA – Not applicable, NR – Not reported, NRS – Numerical rating scale, PSEQ – Pain self-efficacy questionnaire, PSFS - Patient Specific Functional Scale, RCT – Randomised controlled trial, RMDQ – Roland-Morris disability questionnaire, SD – Standard deviation.

GREEN: Study characteristic aligns with the scope

AMBER: Study characteristic partly aligns with the scope

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4 Clinical evidence review

4.1 Overview of methodologies of all included studies

Eight records were identified evaluating 3 technologies: Joint Academy (Arthro Therapeutics Ltd), Phio Engage (EQL Ltd) and SelfBack (SelfBack ApS). The 3 records reporting on SelfBack were associated with the previously included SelfBack RCT (Sandal et al. 2021) and reported subgroup analyses for groups not of interest to the NICE Scope. These records are summarised in Error! Reference source not found. only (Bardal E M et al. 2023, Øverås C K et al., Rughani G et al. 2023).

The remainder of this addendum summarises the 5 prioritised studies. All were retrospective observational studies providing non-comparative data and 3 were conducted in the UK.

One study was described as a mixed methods study and compared a cohort of people with non-specific LBP receiving SelfBack to participants of the standard care MIDAS study, which SelfBack ApS confirmed included people with specific LBP. As the MIDAS comparator group included people with specific back pain without reporting non-specific cases separately and did not report differences in effect size between groups, the SelfBack cohort was extracted as a retrospective case series (SelfBack 2023). A retrospective cohort study compared v1.4.4 of Phio Engage to an earlier version, though information on the earlier version and the duration of use from which data was reported was not reported; only v1.4.4 data was therefore considered eligible, and the study was extracted as a single-arm case series (EQL Ltd [unpublished]).

Three studies were conducted in a primary care referral setting, including 2 UK retrospective case series evaluating Phio Engage (NHS Highland [unpublished]) and SelfBack (SelfBack 2023) and 1 retrospective case series in a Swedish population evaluating Joint Academy (Sirard P 2023). One UK retrospective case series evaluated a technology (Phio Engage) in a self-referral setting (Sandwell and West Birmingham NHS Trust [unpublished]).

In 4 studies patients with acute or chronic LBP were included, none of which reported outcomes by acute or chronic LBP subgroups.

In 1 Phio Engage retrospective case series the location, patient setting and patient population were not clearly reported (EQL Ltd [unpublished]).

No clinical evidence was found for Flok (Flok Health Ltd), Physitrack (Physitrack PLC) or Sword Health (Sword Health).

4.2 Critical appraisal of studies

As specified by the <u>NICE early value assessment interim guidance</u>, no formal risk of bias assessment was conducted.

No comparative studies were available. All studies were retrospective.

The SelfBack case series was provided as an unpublished manuscript. The company noted that due to the small sample size, pain intensity data was unreliable and thus this was not extracted by the EAG (SelfBack 2023). The 2 Phio Engage case series studies reported small sample sizes, potentially limiting their generalisability (NHS Highland [unpublished], Sandwell and West Birmingham NHS Trust [unpublished]). These case series also did not report outcomes at clear timepoints, instead reporting endpoints at participants' last use of the app.

Three studies were conducted in UK NHS populations. The Joint Academy study was conducted in a Swedish primary care referral population and may not be generalisable to a UK NHS setting (Sirard P 2023).

Concomitant treatments were not clearly reported. Two UK studies included participants who were offered the respective apps (Phio Engage and SelfBack) while seeking primary care, though did not clearly report whether the app was offered alone or whether participants received physiotherapy or other concomitant treatments (NHS Highland [unpublished], SelfBack 2023). The other Phio Engage study, in a self-referral population, did not report whether participants received any concomitant treatment (Sandwell and West Birmingham NHS Trust [unpublished]). The Joint Academy case

series reported that patients could receive up to 10 qualified healthcare visits over 12 months in addition to the 3-month Joint Academy treatment (Sirard P 2023).

In 1 Phio Engage retrospective case series, the location, patient setting and patient population were not clearly reported, preventing an assessment of the generalisability of study results (EQL Ltd [unpublished]).

No longer term data was available, as no endpoints beyond 3 months were reported.

4.3 Results from the evidence base

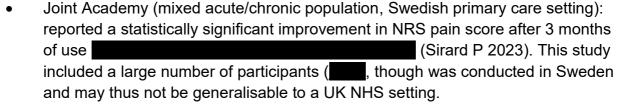
No studies reported pain self-efficacy, time to recovery (acute LBP), patient choice and preference, activation measures, physiotherapy referrals, time on waiting lists, self-removal from waiting lists, reduced pharmacological management, reduced imaging referrals, reduced surgical referrals, discharge rates, emergency department visits, reoccurrence of LBP, health-related quality of life scores or the Oswestry Disability Index. All clinical outcome data are presented in Table 11.2 to Table 11.9.

Pain

Four studies reported pain outcomes. Three studies reported pain outcomes using a 0 to 10 numerical rating scale (NRS) pain score, though timepoints varied. Evidence on the efficacy of digital technologies for improving pain scores was limited.

Two studies reported evidence in primary care referral settings:

•	Phio Engage (mixed acute/chronic, UK primary care setting): reported no
	significant change in NRS pain score from baseline to last use of the app after
	(NHS Highland
	[unpublished]). participants were reported to have experienced a
	clinically significant reduction in pain intensity (defined as a reduction of 27.8% or
	more of the initial pain rating) (NHS Highland [unpublished]). The sample size in
	this study was small, limiting the generalisability of results.



The retrospective data provided in a request for information document reported an average improvement in pain of in users of Phio Engage v1.4.4 between June 30th 2022 and November 1st 2023, though the description did not report how the outcome was measured or at which timepoint it was measured. The patient population, location and setting were also not reported (EQL Ltd [unpublished]).

Functional outcomes

Three studies reported functional outcomes using different measures at varying timepoints. None reported whether findings were considered clinically significant.

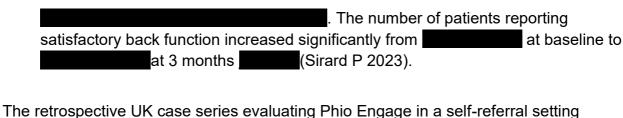
Two studies reported evidence in primary care referral settings:

- Phio Engage (mixed acute/chronic, UK primary care setting): reported a statistically significant improvement in patient specific functional scale (PSFS) aggregate score goal achievement from baseline to last use of the app after (NHS Highland [unpublished]).
- The case series evaluating Joint Academy in a Swedish mixed acute/chronic LBP population in a primary care referral setting reported results for the Chair Stand Test, which records the mean number sit-to-stand repetitions participants could complete in 30 seconds (Sirard P 2023). This study reported a statistically significant improvement from baseline to 3 months

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The retrospective UK case series evaluating Phio Engage in a self-referral setting reported no significant change in PSFS aggregate score goal achievement from baseline to last use of the app after (Sandwell and West Birmingham NHS Trust [unpublished]).

The 2 Phio Engage studies (one in a primary care referral setting, one in a self-referral setting) reported the proportion of patients reporting improvements in PSFS goal achievement score. Across the 2 studies clinically significant improvements were reported and categorised as small improvements (an increase of 1.3 points) as experienced by (NHS Highland [unpublished]) to (Sandwell and West Birmingham NHS Trust [unpublished]) patients, medium improvements (an increase of 2.3 points) by (NHS Highland [unpublished]) to (Sandwell and West Birmingham NHS Trust [unpublished]) patients and large improvements (an increase of more than 2.7 points) by (NHS Highland [unpublished]) to (Sandwell and West Birmingham NHS Trust [unpublished]) patients.

Musculoskeletal Health Questionnaire

One study provided data: the retrospective case series evaluating SelfBack (mixed population, primary care referral setting) reported that pain scores reduced by on the MSKHQ within the first 30 days, but did not report whether this change was significant (SelfBack 2023).

Work Productivity

One study provided data: the retrospective case series evaluating SelfBack (mixed population, primary care referral setting) reported that after 2 weeks patients considered their symptoms "much better/better" compared to before their appointment,

considered them to be the same and considered them "much worse/worse" (SelfBack 2023).

Clinician satisfaction

One study provided information on clinician satisfaction. The UK retrospective case series (SelfBack, mixed acute/chronic population in a primary care referral setting) reported qualitative information from interviews conducted with 5 first contact practitioners,

(SelfBack 2023).

<u>Adherence</u>

2 studies reported adherence. The Swedish retrospective case series (Joint Academy, mixed acute/chronic population in a primary care referral setting) calculated adherence based on participants' use of the app, including self-reported completion of exercises (2 exercises per day) and patient education (2 to 3 text lessons with follow-up questions per week) of the 3-month period calculated as a percentage (Sirard P 2023). Median adherence was with of patients achieving 100% adherence (Sirard P 2023). Adherence was also reported as a mean score and median score and median score. Participants who did not complete three months of treatment were excluded from the analysis, which may contribute to the high adherence rate.

1 retrospective case series study reported that compliance was 52.14% during the first 5 days, 49.43% in the first 7 days and 45.57% in the first 10 days among users of Phio Engage v1.4.4 between June 30th 2022 to November 1st 2023, though neither the definition of compliance, the location or study setting were reported (EQL Ltd [unpublished]).

Patient Experience

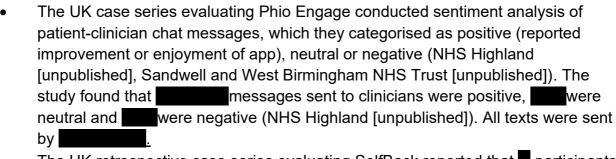
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4 studies reported patient experience using different measures at different timepoints (NHS Highland [unpublished], Sandwell and West Birmingham NHS Trust [unpublished], SelfBack 2023, Sirard P 2023).

Studies conducted in primary care referral settings:



- The UK retrospective case series evaluating SelfBack reported that participants were asked about their symptoms at 2 weeks compared to those prior to their first appointment. felt much better or better, felt the same and felt worse or much worse (SelfBack 2023).
- The Swedish retrospective case series evaluating Joint Academy reported patient satisfaction in the form of a Net Promoter Score (NPS). Participants were asked how likely they were to recommend Joint Academy to others on a scale of 0 to 10, then categorised into critics (0-6 points), passives (7-8 points) and ambassadors (9-10 points). The NPS score was calculated by subtracting the percentage of critics from the percentage of ambassadors to produce a between -100 and +100 where a higher score indicates higher satisfaction (Sirard P 2023). The NPS score at 3 months was (Sirard P 2023).

The case series in a self-referred setting (evaluating Phio Engage) reported that patients sent messages, of which were positive, were neutral and were negative (Sandwell and West Birmingham NHS Trust [unpublished]).

Change in number of appointments

Two studies, both evaluating Phio Engage in UK settings, reported the reduction in the number of physiotherapy follow-up appointments. The case series in a self-referred setting reported that there was an average of follow up physiotherapy appointments saved per patient (Sandwell and West Birmingham NHS Trust [unpublished]). The case series conducted in a primary care setting reported that there were an average of physiotherapy appointments saved per patient (NHS Highland [unpublished]).

5 Adverse events and clinical risk

Adverse events

Adverse events were reported by 2 studies, both evaluating Phio Engage in a primary care (NHS Highland [unpublished]) and self-referral setting (Sandwell and West Birmingham NHS Trust [unpublished]). Both studies reported that arose in the chat feature of Phio Engage where patients reported new/concerning symptoms and were advised by EQL clinicians as a result (in the self-referral setting study and in the primary care referral setting study) (NHS Highland [unpublished], Sandwell and West Birmingham NHS Trust [unpublished]).

One study reported withdrawals. The Swedish retrospective case series evaluating Joint Academy (primary care referral setting) reported that participants who did not use the app for the full 3-month treatment period were excluded, with of those initially recruited excluded for this reason (Sirard P 2023). The authors discuss this as a limitation of the study as no information on these patients or their reasons for discontinuing was collected, noting this might include dissatisfaction with the app (Sirard P 2023).

6 Economic evidence

6.1 Economic evidence

A single set of searches was conducted to identify both clinical and economic evidence for the scoped technologies within this addendum (see Appendix A). Economic evaluations were considered eligible if they reported total costs, effectiveness, incremental analyses, other health economic evaluation outcomes, or measured any relevant cost or resource use associated with the use of non-specific LBP for the scoped technologies. 3 costing studies were considered relevant to these criteria were identified through the company submitted evidence or the search strategy. The costing studies did not contain a full cost-effectiveness analysis but provide relevant economic



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 Table 6.1:
 Narrative summary of economic studies

Study ID and location	Title	Study type	Narrative summary	
Costing studies				

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6.2 Implications for economic modelling

All companies provided a cost for their technology. Each of these technology costs were within the boundaries explored as part of the EAG economic modelling. For Physitrack, Phio Engage and SelfBack, assuming a similar level of effectiveness used in the EAG model, it is plausible that these digital technologies could also be a cost-effective intervention to the NHS. No further early economic modelling has been conducted for these technologies. Details of the previous early economic modelling can be located in Section 8 of the early value assessment report. The cost reported in the early value assessment for SelfBack identified in published literature differs from the cost provided by the company. This is likely due to the average number of licenses required per person. However, this does not lead to any difference in the overall conclusions of the model.

When evidence is collected to bridge current evidence gaps on digital health technologies for non-specific LBP, all technologies in the addendum could be evaluated using the structure suggested in Section 10.3 of the early value assessment report, except for Flok Health. This is discussed further in section 7.2.3.

6.2.1 Joint Academy

It is likely that the early cost-utility model is not representative of the potential economic impact of Joint Academy. This is due to the intervention focusing on replacing face-to-face physiotherapy with digital physiotherapy whereas the early cost-utility model presented in the original early value assessment report focuses on technologies which are more likely to be used as an adjunct to standard care. Additionally, Arthro Therapeutics Ltd has not submitted any evidence on resource use which supports the use of their technology within non-specific LBP, within a UK healthcare setting.

To estimate the potential impact of Joint Academy, the 12-week cost of the technology can be compared to the cost of physiotherapy currently provided by the NHS. The 12 week cost for Joint Academy is expected to cost

covering up to 12 physiotherapy sessions), with standard care physiotherapy currently costing £144 for a

one-to-one session, or £92 for a group session (Jones KWH et al. 2022). Assuming a 50:50 split between group and one-to-one sessions, the average physiotherapy session is estimated to cost £118. As a result, If Joint Academy replaced over face physiotherapy appointments, regardless of any other potential efficiency savings, it could potentially be cost-saving. Clinical feedback as part of the early value assessment indicated that a person would have on average 4 physiotherapy sessions when referred.

The calculations estimated for Joint Academy assume a similar level of effectiveness between Joint Academy and current physiotherapy practices, meaning the wider impact on the healthcare system would be the same. Current evidence suggests that digital physiotherapy may be a similar effectiveness to face-to-face therapy and may lead to higher treatment adherence and patient satisfaction (Hawley-Hague H et al. 2023, Cui D et al. 2023, Lara-Palomo IC et al. 2022). If Joint Academy was more effective or benefited from shorter waiting times (a key value proposition of digital technologies for non-specific LBP) at the same effectiveness as standard care, then this may reduce healthcare costs further, as well as improve quality of life.

6.2.2 Flok Health

The early cost-utility model is not likely to be representative of Flok Health, since it offers to lead the assessment, triage and treatment, effectively replacing a substantial part of the standard care pathway. This differs from all the other technologies, which do not offer a full initial assessment and appropriate triage (unless used in conjunction with other applications). Other technologies would be used through direct referral, or sometimes self-referral, but this would not entail a full assessment service. The cost-effectiveness of Flok Health is likely to be determined by:

- The relative accuracy of their assessment, supported by AI (based on clinical guidelines), compared with standard care.
- Any improvements in the efficiency or waiting time associated with triage and treatment.
- The relative effectiveness of their digital treatments, compared with standard care.
- The cost of Flok Health.

For people referred to physiotherapy, if Flok Health replaced over face-to-face physiotherapy appointments, regardless of any other potential efficiency savings, it could potentially be cost-saving. Other potential savings from Flok Health may stem from more effective triage or faster access to treatment. As a result, this may reduce healthcare costs but also improve people's health-related quality of life. However, evidence is currently limited to determine if the technology would provide these benefits. Further evidence would need to be produced for Flok Health in order to accurately determine the cost-effectiveness, given the uncertainty and lack of evidence for the effectiveness of the technology at each stage of the care pathway.

With regards to future modelling, the model described in the early value assessment report would likely need some adaptation to capture the impact of Flok Health. Although a cohort model driven by pain scores would still be suitable for the treatment and longer-term follow up phases, it may not be able to adequately capture the resource use through assessment and triage. Hence, a decision tree or tunnel states may need to be used to capture the resource use for assessment in the first cycle of the model. Clinical input should also be sought to validate any assumptions made surrounding the assessment part of the care pathway, including the key resource used for the intervention, as well as standard care.

6.2.3 Digital Therapist

Similar to Flok Health, it is likely that the early cost-utility model is not representative of Digital Therapist due to the technology replacing a substantial part of the standard care pathway. Sword Health has provided a cost for their device of approximately

Hence, assuming an average of 4 physiotherapy sessions per person,

Sword Health would need to replace over standard care physiotherapy sessions to be cost-saving, when also taking into account the cost of 30 minutes of NHS physiotherapist time. This is assuming similar effectiveness between Digital Therapist and standard care (face-to-face physiotherapy).

Additionally, Digital Therapist includes optional content, such as cognitive behavioural therapy, through the application. As a result, the combination of services offered by Digital Therapist in one place may make them a more effective service than standard care. However, there is currently no UK based evidence to support Digital Therapist to determine this.

7 Interpretation of the evidence

7.1 Interpretation of the clinical and economic evidence

Key findings from the 5 studies included in this addendum support the main report's findings by providing some early evidence to suggest the digital health technologies may improve pain and function in people with non-specific LBP after being used for between 1 and 3 months. No further support was found for the performance of these technologies by comparison to standard care.

However, results of the 5 included studies were inconsistent. Significant improvements in pain scores were reported by 2 of the 4 studies reporting this outcome (1 in a primary referral setting and 1 in a self-referral setting). The study in a self-referral setting reported that of patients experienced clinically meaningful reductions in pain intensity and a the study in a primary care setting reported of patients experienced clinically meaningful reductions in pain intensity. The same studies also reported significant improvements in function. The study in a self-referral setting reported that experienced at least a small clinically meaningful improvement in PSFS goal achievement, and the study in a self-referral setting reported that experienced at least a small clinically meaningful improvement in PSFS goal achievement.

No adverse events were identified indicating these digital technologies are plausibly safe for treating non-specific LBP. However, 1 study did report a substantial withdrawal rate, with reasons for drop-out not reported.

The EAG considers the clinical evidence identified in this addendum to be of limited quality due to the studies being observational, non-comparative and retrospective, with 3 of 4 studies evaluating 52 or fewer patients (and 1 study not reporting the number of patients). With the exception of pain, outcome measures were generally heterogeneous or measured by only 1 study. Although 3 studies were conducted in UK NHS settings, information on whether the digital health technologies were used alone or in addition to usual care was not clearly reported, which may limit generalisability in addition to their small sample sizes. The Joint Academy case series reported that patients could receive up to 10 healthcare visits (Sirard P 2023), though no other studies reported whether participants received any concomitant treatments. These limitations in study quality are likely to have contributed to the inconsistency in study findings.

7.2 Integration into the NHS

Of the 6 digital health technology providers included within the scope of this addendum, 5 of these are currently used within the NHS, as outlined in section 2.1. Both Phio Engage and Physitrack are not registered as medical devices under CE or UKCA marking, since they claim they do not serve any medical functions. EQL (Phio Engage) has confirmed this previously with the MHRA, whereas Physitrack has had this confirmed by a healthcare regulatory consultancy. The EAG recommends Physitrack also confirm this regulatory status with the MHRA. Only 3 providers have received DTAC compliance. The EAG recommends that the other 3 providers in this addendum seek DTAC compliance if they have not started the process already. Digital technologies described in this addendum are noted to operate across a range of other MSK conditions, beyond non-specific LBP.

Of the technologies listed in this addendum, no concerns are raised by the EAG regarding safety net features. This is because the technologies are either:

- Used after referral from a clinician, who should screen for high-risk conditions.
- Used in conjunction with other risk-based technologies.
- Facilitating digitisation of face-to-face care, meaning a clinician will still be able to assess high-risk conditions.
- Designed to provide their own assessment of the person's condition.

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Clinical risk and suitable referrals remain key criteria for use of the digital technologies considered in the addendum, as described in the early value assessment report. The EAG notes that the same considerations raised previously should also be considered for these technologies, with regards to suitability and risk. Further detail is also provided on the training and resource use considerations in the early value assessment report, which is also applicable to the new technologies considered in this addendum. There is potential that other costs may not have been considered based on the evidence available, such as staff time, which will need to be fully factored into future evaluation.

With regards to the impact on the current care pathway, Flok Health is likely to have a greater impact on the care pathway compared with other technologies considered within the early value assessment report and this addendum. This is because Flok Health can replace a substantial proportion of the care pathway, including assessment, triage and treatment. The suitability of Flok Health should be considered for specific populations who may have difficulties engaging with the technology. Furthermore, additional evidence is key to understand how Flok Health may impact different parts of the care pathway, beyond just treatment outcomes. Further detail on the value proposition of solely treatment-based technologies is provided in the early value assessment report.

7.3 Ongoing studies

Seven ongoing studies were identified in the EAG searches (summarised in Table 7.1) and 6 were reported in company submissions (summarised in Table 7.2). The EAG contacted companies to clarify study populations where it was not clear from the submitted documents whether studies would include data for the eligible population. For those companies that did not respond, the EAG considered their studies to partially meet the population eligibility criteria since relevant subgroup data might be available.

All 6 companies listed ongoing studies in their respective RFI submissions. Studies from Flok Health Ltd, Physitrack and SelfBack ApS are summarised in Table 7.2. Arthro Therapeutics Ltd listed a number of ongoing studies which were in ineligible populations (mostly osteoarthritis), which for this reason are not listed in Table 7.2. EQL Ltd did not reference individual ongoing studies, but stated that qualitative and

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quantitative evaluation of the Phio system is ongoing across the breadth of all appropriate MSK presentations, with new evidence expected to be available from Q3 2024. Sword Health Ltd listed an ongoing trial that was found in the EAG searches and this is summarised in Table 7.1 (Sword Health 2022).

Table 7.1: Ongoing studies list from EAG searches

Ongoing study (EAG searches)	Alignment with scope	Outcome data for economic model	Indicated trial end date
Author (year): The Sydney Musculoskeletal Bone & Joint Health Alliance, 2018 (The Sydney Musculoskeletal Bone & Joint Health Alliance 2018) Study design: RCT Company: Physitrack Country: Australia	culoskeletal Bone & the Health Alliance, 2018 e Sydney culoskeletal Bone & the Health Alliance, 2018 e Sydney culoskeletal Bone & the Health Alliance 2018) dy design: RCT chapters: Could not be assessed Comparator: Usual care GREEN Participants: Knee Osteoarthritis and non-specific chronic low back pain AMBER Setting: Primary care GREEN Outcomes: Could not be assessed		NR
Author (year): NSW Agency For Clinical Innovation Research Grant Scheme, 2021 (Joshua Zadro 2021) Study design: RCT Company: Physitrack Country: Australia	Intervention: Physitrack plus other self-management assistance GREEN Comparator: Usual care GREEN Participants: Non-specific LBP or radicular LBP/sciatica AMBER Setting: Primary care GREEN Outcomes: Could not be assessed	NR	NR
Author (year): Hunter New England Local Health District, 2021 (John Hunter Hospital 2022) Study design: RCT Company: Physitrack Country: USA	Intervention: Physitrack or paper printout AMBER Comparator: Usual care GREEN Participants: Patients referred for Physiotherapy management of a Shoulder, Hip, Knee or Lower back complaint AMBER Setting: Primary care GREEN Outcomes: Could not be assessed	NR	NR

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Author (year): Sword Health, SA, 2019 (John Hunter Hospital 2022) Study design: Prospective cohort Company: Sword Health	Intervention: Sword Health GREEN Comparator: NA GREEN Participants: Patients suffering from musculoskeletal conditions including, but not limited to, shoulder pain (tendinitis/impingement/bursitis), neck pain, low back pain, knee or hip pain/osteoarthritis AMBER Outcomes: Could not be assessed	NR	NR
Author (year): Sword Health, SA, 2022 (John Hunter Hospital 2022) Study design: Prospective cohort Company: Sword Health	Intervention: Sword Health GREEN Comparator: NA GREEN Participants: Acute (<12 weeks) or chronic (>12 weeks) musculoskeletal pain involving any of the following body areas: neck, upper and lower back, shoulder, elbow, wrist/hand, hip, knee, ankle OR Recovering from MSK surgery involving the above body areas with indication from their surgeon to engage in a physical therapy program AMBER	NR	2027
Author (year): University of Sydney, 2018 (University of Sydney 2018) Study design: RCT Company: Physitrack Intervention: Physitrack GREEN Comparator: Usual care GREEN Participants: Patients with non-specific LBP GREEN Outcomes: Could not be assessed		NR	NR
Author (year): Hasselt University, 2022 (University of Sydney 2018) Study design: Prospective cohort Company: Physitrack Intervention: Physitrack GREEN Comparator: NA GREEN Participants: Patients with chronic LBP of a nonspecific origin LBP GREEN Outcomes: Could not be assessed		NR	NR

 $\label{eq:key:lbp-low-back-pain} \ \ NA-Not\ applicable,\ NR-Not\ reported,\ RCT-Randomised\ controlled\ trial.$

GREEN: Study characteristic aligns with the scope **AMBER:** Study characteristic partly aligns with the scope

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Studies identified through company submissions

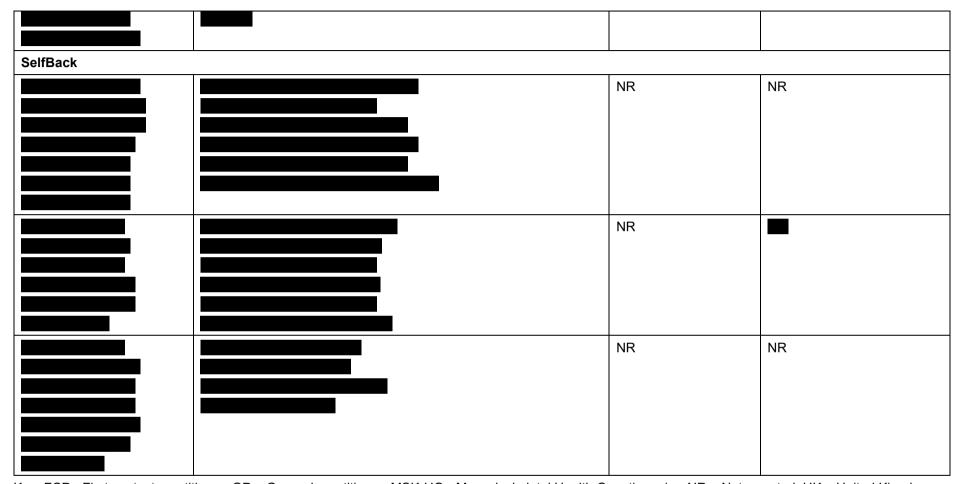
Table 7.2: Ongoing studies list from company submissions

Ongoing study (company submissions)	Alignment with scope	Outcome data for economic model	Indicated trial end date
Flok Health			
		NR	NR
Physitrack		1	
		NR	NR
		NR	NR

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 $Key: FCP - First\ contact\ practitioner,\ GP-General\ practitioner,\ MSK-HQ-Musculoskeletal\ Health\ Questionnaire,\ NR-Not\ reported,\ UK-United\ Kingdom.$

GREEN: Study characteristic aligns with the scope

AMBER: Study characteristic partly aligns with the scope

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8 Evidence gap analysis

The same outcomes and evidence gaps to those summarised in the original early value assessment report were also identified by the studies considered in this addendum, with the exception of change in physiotherapy appointments which is now reported by 2 observational studies. The EAG consider the existing summary of evidence gaps and recommendations for evidence generation reported in the EAG report to remain applicable.

Flok Health Ltd and Sword health are likely to require further evidence compared to other technology providers to identify the effectiveness of different components of their technology. This is because both applications can facilitate assessment, triage, and treatment for a person with non-specific LBP. Therefore, the evidence generated must be able to demonstrate that the technologies are effective at each point of the care pathway. This includes outcomes such as the accuracy of triage, wait times for treatment and other resource use compared with standard care.

9 Conclusions

The additional information presented to the EAG does not change the conclusions of the early value assessment report. The available clinical and economic evidence suggests that digital technologies for non-specific LBP may be beneficial to the NHS in England. However, there is still a lack of comparable evidence from a UK NHS setting for digital technologies. Further detail is provided in the early value assessment report.

10 References

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11 Appendices

Appendix A - Search methods

A MEDLINE (OvidSP) search strategy designed to identify to identify studies of the named digital technologies in **Error! Reference source not found.** is presented below. This search was conducted to supplement the searches carried out for the previous report.

The strategy was devised using a free text search terms in the Title, Abstract and Keyword Heading Word fields. Searches were not restricted by study design or outcome so were appropriate to retrieve both clinical and economic evidence.

The strategy excluded animal studies from MEDLINE using a standard algorithm (search line 8). The strategy also excluded some ineligible publication types which are unlikely to yield relevant study reports (editorials, news items and case reports) and records with the phrase 'case report' in the title (search line 9).

Reflecting the eligibility criteria, the strategy was restricted to studies published in English (search line 12). The strategy was not limited by publication date.

The final Ovid MEDLINE strategy was peer-reviewed before execution by a second Information Specialist. Peer review considered the appropriateness of the strategy for the review scope and eligibility criteria, inclusion of key search terms, errors in spelling, syntax and line combinations and application of exclusions.

Search limitations

A potential limitation to the search is that records must explicitly report the name of the company or intervention in the fields being searched. The impact of this limitation is mitigated by the fact that this search was conducted as a supplementary search to those carried out for the previous report. The searches for that report were designed to identify studies of digital technologies for managing low back pain using a wider variety of search terms.

Resources searched

We conducted the literature search in the databases and information resources shown in Table A.1.

Table A.1: Databases and information sources searched

Resource	Interface / URL		
Databases			
MEDLINE(R) ALL	OvidSP		
Embase	OvidSP		
Cochrane Database of Systematic Reviews(CDSR)	Cochrane Library/Wiley		
Cochrane Central Register of Controlled Trials (CENTRAL)	Cochrane Library/Wiley		
Conference Proceedings Citation Index - Science (CPCI-S)	Web of Science		
NHS Economic Evaluation Database (NHS EED)	https://www.crd.york.ac.uk/CRDWeb/HomePage.asp		
EconLit	OvidSP		
Trials Registers			
ClinicalTrials.gov	https://clinicaltrials.gov/		
WHO International Clinical Trials Registry Platform (ICTRP)	https://trialsearch.who.int/		
Other			
Reference list checking	n/a		
Company submissions	n/a		

The trials register sources listed above (ClinicalTrials.gov and ICTRP) were searched to identify information on studies in progress.

Reflecting the eligibility criteria, records indexed as preprints were excluded from Embase search results.

We also checked included studies lists of any industry submissions to NICE for additional eligible studies.

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Running the search strategies and downloading results

We conducted searches using each database or resource listed above, translating the agreed Ovid MEDLINE strategy appropriately. Translation included consideration of differences in database interfaces and functionality, in addition to variation in indexing languages and thesauri. The final translated database strategies were peer-reviewed by a second Information Specialist. Peer review considered the appropriateness of the translation for the database being searched, errors in syntax and line combinations, and application of exclusions.

Where possible, we downloaded the results of searches in a tagged format and loaded them into bibliographic software (EndNote) (Clarivate 2021). The results were deduplicated using several algorithms and the duplicate references held in a separate EndNote database for checking if required. Results from resources that did not allow export in a format compatible with EndNote were saved in Word or Excel documents as appropriate and manually deduplicated.

Literature search results

The searches were conducted on 7 November 2023 identified 202 records (Table A.2). Following deduplication, 168 records were assessed for relevance.

Table A.2:Literature search results

Resource	Number of records identified
Databases	
MEDLINE	38
Embase	75
Cochrane Database of Systematic Reviews (CDSR)	0
Cochrane Central Register of Controlled Trials (CENTRAL)	46
Conference Proceedings Citation Index - Science (CPCI-S)	24
NHS Economic Evaluation Database (NHS EED)	0
EconLit	2
Total records identified through database searching	185
Trials Registers	
ClinicalTrials.gov.	10
WHO International Clinical Trials Registry Portal (ICTRP)	7
Total records identified through trials register searching	17
Other sources	
Reference list checking	
Company evidence	10
Total additional records identified through other sources	0
Total number of records retrieved	212
Total number of records after deduplication	168

Search strategies

A.1: Source: MEDLINE ALL

Interface / URL: OvidSP

Database coverage dates: 1946 to 6 November 2023

Search date: 7 November 2023

Retrieved records: 38

Search strategy:

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- 1 (eql or eqltm or eqlr).ti,ab,kf,ot. 24
- 2 phio engage*.ti,ab,kf,ot. 0
- 3 (sword health or sword healthr or sword healthtm).ti,ab,kf,ot. 3
- 4 (flok health or flok healthr or flok healthtm).ti,ab,kf,ot. 0
- 5 (physitrack* or physiapp*).ti,ab,kf,ot. 7
- 6 (joint academy* or arthro therapeutics*).ti,ab,kf,ot. 11
- 7 or/1-6 45
- 8 exp animals/ not humans/ 5168219
- 9 (news or editorial or case reports).pt. or case report.ti. 3303804
- 10 or/8-9 8407041
- 11 7 not 10 41
- 12 limit 11 to english language 38

A2: Source: Embase

Interface / URL: OvidSP

Database coverage dates: 1974 to 6 November 2023

Search date: 7 November 2023

Retrieved records: 75

Search strategy:

1 (eql or eqltm or eqlr).ti,ab,kf,dq,dv,my,ot.37

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- 2 phio engage*.ti,ab,kf,dq,dv,my,ot. 0
- 3 (sword health or sword healthr or sword healthtm).ti,ab,kf,dq,dv,my,ot. 4
- 4 (flok health or flok healthr or flok healthtm).ti,ab,kf,dq,dv,my,ot. 0
- 5 (physitrack* or physiapp*).ti,ab,kf,dq,dv,my,ot. 11
- 6 (joint academy* or arthro therapeutics*).ti,ab,kf,dq,dv,my,ot. 37
- 7 or/1-6 89
- 8 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ 6842259
- 9 editorial.pt. or case report.ti. 1171952
- 10 preprint.pt. 89667
- 11 or/8-10 8053505
- 12 7 not 11 79
- 13 limit 12 to english language 75

A.3: Source: Cochrane Database of Systematic Reviews (CDSR)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 11 of 12,

November 2023

Search date: 7 November 2023

Retrieved records: 0

Search strategy:

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- #1 (eql or eqltm or eqlr):ti,ab,kw 133
- #2 phio next engage*:ti,ab,kw 0
- ("sword health" or "sword healthr" or "sword healthtm"):ti,ab,kw #3 2
- ("flok health" or "flok healthr" or "flok healthtm"):ti,ab,kw #4 0
- #5 (physitrack* or physiapp*):ti,ab,kw 38
- #6 (joint next academy* or arthro next therapeutics*):ti,ab,kw
- #7 #1 or #2 or #3 or #4 or #5 or #6 in Cochrane Reviews, Cochrane Protocols0

Source: Cochrane Central Register of Controlled Trials (CENTRAL)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 10 of 12,

October 2023

Search date: 7 November 2023

Retrieved records: 46

Search strategy:

Terms for the company name "EQL" were not currently interpreted by the interface. These terms were combined with the terms for LBP used in the original report.

- #1 (eql or eqltm or eqlr) 136
- #2 phio next engage* 0
- #3 ("sword health" or "sword healthr" or "sword healthtm") 2
- #4 ("flok health" or "flok healthr" or "flok healthtm") 0

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- #5 (physitrack* or physiapp*) 38
- #6 (joint next academy* or arthro next therapeutics*) 6
- #7 #2 or #3 or #4 or #5 or #6 46
- #8 [mh ^"back pain"] 2940
- #9 [mh ^"low back pain"] 5955
- #10 ((lumbar or lumbosacral or "lumbo sacral" or back) near/5 (pain* or ache* or neuropath* or neuralgi*)) 21018
- #11 (backache* or lumbago or backpain*) 5031
- #12 #8 or #9 or #10 or #11 23773
- #13 #1 and #12 0
- #14 #7 or #13 in Trials 46

A.5: Source: Conference Proceedings Citation Index - Science (CPCI-S)

Interface / URL: Web of Science

Database coverage dates: 1990 to present

Search date: 7 November 2023

Retrieved records: 24

Search strategy:

All lines were searched in the advanced interface with the "Exact search" setting switched on.

1 TS=(eql OR eqltm OR eqlr) 21

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- 2 TS="phio engage*" 0
- TS=("sword health" OR "sword healthr" OR "sword healthtm")
- 4 TS=("flok health" OR "flok healthr" OR "flok healthtm")0
- 5 TS=(physitrack* OR physiapp*) 0
- 6 TS=("joint academy*" OR "arthro therapeutics*") 3
- 7 #6 OR #5 OR #4 OR #3 OR #2 OR #1 24
- 8 LA=(English) 12,113,176
- 9 #7 AND #8 24

A.6: Source: NHS Economic Evaluation Database (NHS EED)

Interface / URL: https://www.crd.york.ac.uk/CRDWeb

Database coverage dates: Information not found. Bibliographic records were published on NHS EED until 31st March 2015. Searches of MEDLINE, Embase, CINAHL, PsycINFO and PubMed were continued until the end of the 2014.

Search date: 7 November 2023

Retrieved records: 0

Search strategy:

- 1 (eql OR eqltm OR eqlr) 0
- 2 (phio engage*) 0
- 3 (sword health OR sword healthr OR sword healthtm) 0
- 4 (flok health OR flok healthr OR flok healthtm) 0

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- 5 (physitrack* OR physiapp*) 0
- 6 (joint academy* OR arthro therapeutics*) 0
- 7 #1 OR #2 OR #3 OR #4 OR #5 OR #6 0

A.7: Source: Econlit

Interface / URL: OvidSP

Database coverage dates: 1886 to 2 November 2023

Search date: 7 November 2023

Retrieved records: 2

Search strategy:

- 1 (eql or eqltm or eqlr).af. 2
- 2 phio engage*.af. 0
- 3 (sword health or sword healthr or sword healthtm).af. 0
- 4 (flok health or flok healthr or flok healthtm).af. 0
- 5 (physitrack* or physiapp*).af. 0
- 6 (joint academy* or arthro therapeutics*).af. 0
- 7 or/1-6 2
- 8 limit 7 to english 2

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A.8: Source: ClinicalTrials.gov

Interface / URL: https://clinicaltrials.gov/ct2/home

Database coverage dates: Information not found. ClinicalTrials.gov was created as a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA). The site was made available to the public in February 2000.

Search date: 7 November 2023

Retrieved records: 10

Search strategy:

The search was conducted using the Expert interface at the following URL:

https://classic.clinicaltrials.gov/ct2/results/refine?show_xprt=Y

To increase the specificity the intervention terms were combined with the terms for LBP used in the original report.

((eql OR eqltm OR eqlr OR "phio engage" OR "phio engager" OR "phio engagetm" OR "sword health" OR "sword healthr" OR "sword healthtm" or "flok health" OR "flok healthtm" OR physitrack OR physitrackr OR physitracktm OR physiapp OR physiappr OR physiapptm OR "joint academy" OR "joint academyr" OR "joint academyr" OR "arthro therapeutics" OR "arthro therapeuticsr" OR "arthro therapeuticstm") AND (((lumbar OR lumbosacral OR lumbo-sacral OR back) AND (pain OR pains OR painful OR ache OR aches OR neuropathy OR neuropathies OR neuropathic OR neuralgic OR neuralgia OR neuralgias)) OR (backache OR backaches OR lumbago OR backpain OR backpains)))

= 10 studies

A.9: Source: WHO International Clinical Trials Registry Portal (ICTRP)

Interface / URL: https://trialsearch.who.int/

Database coverage dates: Information not found. On the date of search, files had been

imported from data providers between August 2023 and October 2023.

Search date: 7 November 2023

Retrieved records: 7

Search strategy:

The search was run with 'Without Synonyms' selected. To increase the specificity the

intervention terms were combined with the terms for LBP used in the original report.

((((lumbar OR lumbosacral OR lumbo-sacral OR back) AND (pain* OR ache* OR

neuropath* OR neuralgi*)) OR (backache* OR lumbago OR backpain*)) AND (eql OR

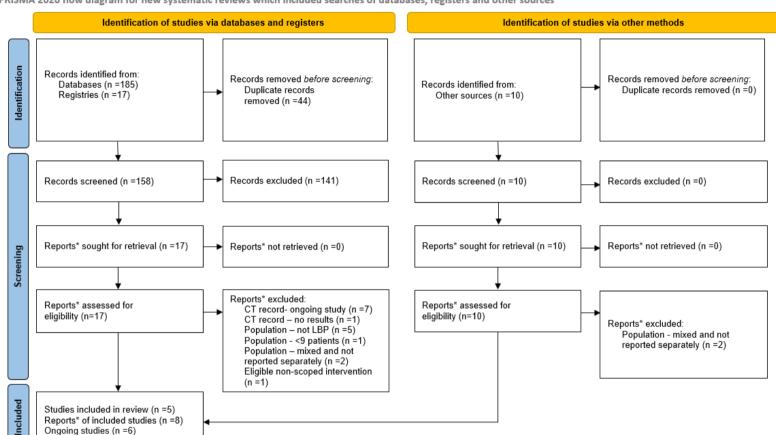
egltm OR eglr OR "phio engage*" OR "sword health" OR "sword healthr" OR "sword

healthtm" OR "flok health" OR "flok healthtm" OR physitrack* OR

physiapp* OR "joint academy*" OR "arthro therapeutics*"))

= 7 records

PRISMA diagram



PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources

Adapted from: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. For more information, visit: http://www.prisma-statement.org/

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^{*&}quot;Note that a "report" could be a journal article, preprint, conference abstract, study register entry, clinical study report, dissertation, unpublished manuscript, government report or any other document providing relevant information": https://www.bmj.com/content/372/bmj.n71.

Appendix B – List of studies excluded at full text assessment (n=19)

Table 11.1: List of excluded studies (N=19)

References	Exclusion reason
Arensman R, Kloek C, Pisters M, Koppenaal T, Ostelo R, Veenhof C. Patient perspectives on using a smartphone app to support home-based exercise during physical therapy treatment: Qualitative study. JMIR Hum Factors. 2022.9(3):e35316. doi: https://dx.doi.org/10.2196/35316	Population – Less than 9 patients
Cui D, Janela D, Costa F, Molinos M, Areias A C, Moulder R G, et al. Randomized-controlled trial assessing a digital care program versus conventional physiotherapy for chronic low back pain. NPJ Digital Medicine 2023.6(1):121. doi: https://doi.org/10.1038/s41746-023-00870-3	Population – Mixed and outcomes not reported separately
Deakin University. Feasibility and effects of a pragmatic home-based resistance 'exercise snacking' program on physical function in older adults living independently. Identifier: ACTRN12621001538831. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2021. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02349089/full.	Population – Not LBP
Hasselt University. Technology supported high intensity training at home for persons with chronic low back pain. Identifier: NCT05234008. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2022. Available from https://classic.clinicaltrials.gov/show/NCT05234008.	CT record – Ongoing study
Hörder H, Nero H, Ignjatovic M, Kiadaliri A, Lohmander L S, Dahlberg L E, et al. Digitally delivered exercise and education treatment program for low back pain: Longitudinal observational cohort study. JMIR Rehabil Assist Technol. 2022.9(2):1-15. doi: http://dx.doi.org/10.2196/38084	Population – Mixed and outcomes not reported separately
John Hunter Hospital. Evaluating the impact of electronic exercise prescription software on compliance with a physiotherapy program. Identifier: ACTRN12622000098730. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2022. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02376322/full.	CT record – Ongoing study
Joint Academy. Digitally delivered exercise and education treatment for low back pain: 3 months follow-up. Identifier: NCT05226156. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2021. Available from https://classic.clinicaltrials.gov/show/NCT05226156.	Population – Mixed and outcomes not reported separately
Joshua Zadro. Stratified care integrated with eHealth for low back pain: a feasibility randomised controlled trial. Identifier: ACTRN12621001104842. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and	CT record – Ongoing study

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Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2021. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02327214/full.	
Keel S, Schmid A, Keller F, Schoeb V. Investigating the use of digital health tools in physiotherapy: Facilitators and barriers. Physiother Theory Pract. 2023.39(7):1449-68. doi: https://dx.doi.org/10.1080/09593985.2022.2042439	Population – Not LBP
Robson H. PhysioNow - A digital musculoskeletal patient self-assessment application, transforming access to MSK physiotherapy services. Physiotherapy. 2022.114(Suppl 1):e102-e03. doi: https://dx.doi.org/10.1016/j.physio.2021.12.049	Eligible non-scoped intervention
Sword Health. Digital care program for chronic low back pain. Identifier: NCT04808141. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2021. Available from https://classic.clinicaltrials.gov/show/NCT04808141.	Population – Mixed and outcomes not reported separately
Sword Health. Digital care programs for musculoskeletal health. Identifier: NCT05417685. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2022. Available from https://classic.clinicaltrials.gov/show/NCT05417685.	CT record – Ongoing study
Sword Health. Home-based exercise rehabilitation with a novel digital biofeedback system for chronic low back pain. Identifier: NCT04401683. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2020. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02124898/full.	CT record – No results
Sword Health. SWORD health patient registry. Identifier: NCT04819022. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2019. Available from https://classic.clinicaltrials.gov/show/NCT04819022.	CT record – Ongoing study
The Sydney Musculoskeletal Bone & Joint Health Alliance. EHealth to empower patients with musculoskeletal pain in rural Australia (EMPoweR) a randomized controlled trial. Identifier: ACTRN12618001494224. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2018. Available from https://anzctr.org.au/ACTRN12618001494224.aspx.	CT record – Ongoing study
The University of Melbourne. Patient adherence to physiotherapy exercise programs: Effect of a web-based exercise programming system compared to usual physiotherapy exercise delivery. Identifier: ACTRN12615001011572. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney: National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2015. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02439790/full.	Population – Not LBP
University of Bern. Exercise intervention for employees of the university of Bern. Identifier: NCT05676528. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2022. Available from https://classic.clinicaltrials.gov/show/NCT05676528.	Population – Not LBP
University of Sydney. CONNECT: Telecare health coaching management of low back pain in primary care to improve disability. Identifier: ACTRN12618001628235. In: Australian New Zealand Clinical Trials Registry [internet]. Sydney:	CT record – Ongoing study

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National Health and Medical Research Council (NHMRC) Clinical Trials Centre - University of Sydney: 2018. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02445036/full.	
Wanless B. Implementation of a web-based and smartphone based exercise prescription program in MSK Physiotherapy. Physiotherapy. 2017.103(Suppl 1):e124-e25. doi: https://dx.doi.org/10.1016/j.physio.2017.11.177	Population – Not LBP

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Appendix C – Clinical outcome tables

Table 11.2: Intermediate outcomes 1

Study name and location	Technology name	Pain self-efficacy	Change in number appointments		
Phio Engage					
EQL Ltd 2023 (EQL Ltd [unpublished])	Phio Engage	NR	NR		
Location: NR					
NHS Highland [unpublished] (NHS Highland [unpublished])	Phio Engage	NR	NR		
Location: UK					
NHS Sandwell and West Birmingham (Sandwell and West Birmingham NHS Trust [unpublished])	Phio Engage	NR	NR		
Location: UK					
SelfBack					
ICS Stoke on Trent [unpublished](SelfBack 2023)	SelfBack	NR	NR		
Location: UK					

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Study name and location	Technology name	Pain self-efficacy	Change in number appointments		
Joint Academy					
Sirard 2023 (Sirard P 2023) Joint Academy NR NR					
Location: Sweden					

Key: ICS – Integrated Care System, NHS – National Health Service, NR – Not reported, PP – Per protocol, UK – United Kingdom.

Table 11.3: Intermediate outcomes 2

Study name and location	Technology name	Time to recovery (for acute LBP)	Patient choice and preference	Work productivity/Return to full activity		
Phio Engage	Phio Engage					
EQL Ltd 2023 (EQL Ltd [unpublished])	Phio Engage	NR	NR	NR		
Location: NR						
NHS Highland [unpublished] (NHS Highland [unpublished])	Phio Engage	NR	NR	NR		
Location: UK						
NHS Sandwell and West Birmingham	Phio Engage	NR	NR	NR		
(Sandwell and West Birmingham NHS Trust [unpublished])						
Location: UK						
SelfBack						

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Study name and location	Technology name	Time to recovery (for acute LBP)	Patient choice and preference	Work productivity/Return to full activity
ICS Stoke on Trent [unpublished] (SelfBack 2023)	SelfBack	NR	NR	
Location : UK				
Joint Academy				
Sirard 2023 (Sirard P 2023)	Joint Academy	NR	NR	NR
Location: Sweden				

Key: ICS – Integrated Care System, NHS – National Health Service, NR – Not reported, PP – Per protocol, UK - United Kingdom.

Table 11.4: Intermediate outcomes 3

Study name and location	Technology name	Intervention adherence and completion	Activation measures (indicators of app use over study period)	Treatment satisfaction and engagement (patient opinion)	Intervention- related adverse effect	Withdrawals/ discontinuations	Clinician satisfaction
Phio Engage			I		1		
EQL Ltd 2023 (EQL Ltd [unpublished]) Location: NR	Phio Engage		NR	NR	NR	NR	NR

Study name and location	Technology name	Intervention adherence and completion	Activation measures (indicators of app use over study period)	Treatment satisfaction and engagement (patient opinion)	Intervention- related adverse effect	Withdrawals/ discontinuations	Clinician satisfaction
NHS Highland [unpublished] (NHS Highland [unpublished]) Location: UK	Phio Engage	NR	NR	NR		NR	NR

Study name and location	Technology name	Intervention adherence and completion	Activation measures (indicators of app use over study period)	Treatment satisfaction and engagement (patient opinion)	Intervention- related adverse effect	Withdrawals/ discontinuations	Clinician satisfaction
NHS Sandwell and West Birmingham (Sandwell	Phio Engage	NR	NR	NR		NR	NR
and West Birmingham NHS Trust [unpublished])							
Location: UK							

SelfBack

Study name and location	Technology name	Intervention adherence and completion	Activation measures (indicators of app use over study period)	Treatment satisfaction and engagement (patient opinion)	Intervention- related adverse effect	Withdrawals/ discontinuations	Clinician satisfaction
ICS Stoke on Trent [unpublished] (SelfBack 2023) Location: UK	SelfBack	NR	NR	NR	NR	NR	

Joint Academy



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Study name and location	Technology name	Intervention adherence and completion	Activation measures (indicators of app use over study period)	Treatment satisfaction and engagement (patient opinion)	Intervention- related adverse effect	Withdrawals/ discontinuations	Clinician satisfaction

Key: FCP – First contact practitioner, ICS – Integrated Care System, IQR – Interquartile range, NHS – National Health Service, NPS – Net Promoter Score, NR – Not reported, PP – Per protocol, SD – Standard deviation, UK – United Kingdom.

Table 11.5: Clinical outcomes 1

Study name and location	Technology name	Physiotherapy referrals	Treatment waiting list	Self-removal from waiting list
Phio Engage				1
EQL Ltd 2023 (EQL Ltd [unpublished])	Phio Engage	NR	NR	NR
Location: NR				
NHS Highland [unpublished] (NHS Highland [unpublished])	Phio Engage		NR	NR
Location: UK				
NHS Sandwell and West Birmingham (Sandwell and West Birmingham NHS Trust [unpublished])	Phio Engage		NR	NR
Location : UK				
SelfBack		,		1
ICS Stoke on Trent [unpublished] (SelfBack 2023)	SelfBack	NR	NR	NR
Location: UK				

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Study name and location	Technology name	Physiotherapy referrals	Treatment waiting list	Self-removal from waiting list			
Joint Academy							
Sirard 2023 (Sirard P 2023)	Joint Academy	NR	NR	NR			
Location: Sweden							

Key: ICS – Integrated Care System, NHS – National Health Service, NR – Not reported, PP – Per protocol, UK – United Kingdom.

Table 11.6: Clinical outcomes 2

Study name and location	Technology name	Reduced pharmacological management	Reoccurrence of LBP	Reduced imaging referrals
Phio Engage				
EQL Ltd 2023 (EQL Ltd [unpublished])	Phio Engage	NR	NR	NR
Location: NR				
NHS Highland [unpublished] (NHS Highland [unpublished])	Phio Engage	NR	NR	NR
Location: UK				
NHS Sandwell and West Birmingham (Sandwell and West Birmingham NHS Trust [unpublished])	Phio Engage	NR	NR	NR
Location: UK				
SelfBack				
ICS Stoke on Trent [unpublished](SelfBack 2023)	SelfBack	NR	NR	NR
Location: UK				

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Study name and location	Technology name	Reduced pharmacological management	Reoccurrence of LBP	Reduced imaging referrals		
Joint Academy						
Sirard 2023 (Sirard P 2023)	Joint Academy	NR	NR	NR		
Location: Sweden						

Key: ICS – Integrated Care System, NHS – National Health Service, NR – Not reported, PP – Per protocol, UK – United Kingdom.

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Table 11.7: Clinical outcome 3

Study name and location	Technology name	Discharge rate	Surgical referrals	Emergency department attendances				
Phio Engage	Phio Engage							
EQL Ltd 2023 (EQL Ltd [unpublished])	Phio Engage	NR	NR	NR				
Location: NR								
NHS Highland [unpublished] (NHS Highland [unpublished])	Phio Engage	NR	NR	NR				
Location : UK								
NHS Sandwell and West Birmingham	Phio Engage	NR	NR	NR				
(Sandwell and West Birmingham NHS Trust [unpublished])								
Location: UK								
SelfBack								
ICS Stoke on Trent [unpublished](SelfBack 2023)	SelfBack	NR	NR	NR				
Location: UK								

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Study name and location	Technology name	Discharge rate	Surgical referrals	Emergency department attendances
Joint Academy				
Sirard 2023 (Sirard P 2023)	Joint Academy	NR	NR	NR
Location: Sweden				

Key: ICS – Integrated Care System, NHS – National Health Service, NR – Not reported, PP – Per protocol, UK – United Kingdom.

Table 11.8: Patient-reported outcomes 1

Study name and location	Technology name	Functional outcomes	Pain
Phio Engage			
EQL Ltd 2023 (EQL Ltd [unpublished]) Location: NR	Phio Engage	NR	
NHS Highland [unpublished] (NHS Highland [unpublished]) Location: UK	Phio Engage		

Study name and location	Technology name	Functional outcomes	Pain
NHS Sandwell and West Birmingham (Sandwell and West Birmingham NHS Trust [unpublished]) Location: UK	Phio Engage (n = 52)		
SelfBack			
ICS Stoke on Trent [unpublished](SelfBack 2023)	SelfBack	NR	NR
Location: UK			
Joint Academy	1	1	

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Study name and location	Technology name	Functional outcomes	Pain
Sirard 2023 (Sirard P 2023) Location: Sweden	Joint Academy (n=3,643)	Function (Chair Stand Test, sit-to-stand repetitions in 30 second) Change from baseline at 3 months, mean (SE): 5.13 (0.08) (effect size: 1.1; p <0.001) Patients reporting satisfactory back function 678/3643 (18.6%) 1732/3643 (47.6%) The McNemar test showed a significant difference in the proportion of participants reporting	Pain (NRS, higher scores indicate worse pain) Change from baseline at 3 months, mean (SE): -1.85 (0.03) (effect size: -0.9; p <0.001).
		satisfactory back function at baseline after three months of treatment, $X^2 = 852$ (degree of freedom 1), p<0,001.	

Key: BL –Baseline, ICS – Integrated Care System, IQR – Interquartile range, NHS – National Health Service, NR – Not reported, NRS – Numerical Rating Scale, PP – Per protocol, PSFS – Patient Specific Functional Scale, SD – Standard deviation, SE – Standard error, UK – United Kingdom.

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Table 11.9: Patient-reported outcomes 2

Study name and location	Technology name	Health- related quality of life	Musculoskeletal health questionnaire	Back specific disability score (Oswestry Disability Index for LBP)	Patient experience
Phio Engage		1			
EQL Ltd 2023 (EQL Ltd [unpublished])	Phio Engage	NR	NR	NR	NR
Location: NR					
NHS Highland [unpublished] (NHS Highland [unpublished]) Location: UK	Phio Engage	NR	NR	NR	
NHS Sandwell and West Birmingham (Sandwell and West Birmingham NHS Trust [unpublished])	Phio Engage	NR	NR	NR	
Location: UK					

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Study name and location	Technology name	Health- related quality of life	Musculoskeletal health questionnaire	Back specific disability score (Oswestry Disability Index for LBP)	Patient experience	
ICS Stoke on Trent [unpublished] (SelfBack 2023) Location: UK	NR	NR		NR		
SupportBack	SupportBack					
Sirard 2023 (Sirard P 2023)	Joint Academy	NR	NR	NR	NR	
Location: Sweden						

Key: ICS – Integrated Care System, MSK-HQ - Musculoskeletal Health Questionnaire, NHS – National Health Service, NR – not reported, UK – United Kingdom.

