GID-HTE10021 Digital technologies for managing low back pain

Medical technologies advisory committee: 22 Sept 2023

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Digital technologies for managing low back pain

The following slides provide an overview of the external assessment group (EAG) report for this topic. Not all these slides will be presented at the committee meeting but the main information in this set of slides will be summarised. We have tried not to repeat information found in the other documents and references can be found in the slide notes.

Key documents in this assessment include:

- The final scope - contains the decision problem for the assessment
- The external assessment report (EAR)* - assessment of the included technologies by the EAG. The report has a more detailed executive summary which provides an overview of the EAG's work and links to the relevant sections of the report

The slides contain information that has been supplied in confidence. Academic in confidence information is underlined and highlighted in yellow and commercial in confidence information in blue

* These documents are in the Committee pack and will be published at consultation

Technology purpose and unmet need

- The aim of the digital technologies for managing LBP is to provide rapid access to specialist advice and guidance and also give individuals the flexibility to complete in their own time.
- These technologies can be used by those with either acute or chronic LBP and may support the management of LBP through different points in the care pathway or different treatments
- The support provided by digital technologies could include information, education, advice, psychological therapies or further signposting of resources
- These technologies may reduce primary and secondary care resource use while also supporting quicker recovery
- Digital technologies may have a ‘safety net’ feature designed to capture people with specific LBP requiring a different treatment pathway. The importance of this depends on factors such as where the technology is placed in the care pathway

The technologies

9 digital technologies for managing LBP were included in the assessment:

- ACT for PAIN
- Ascenti Reach
- getUBetter
- Hinge Health Digital MSK clinic
- Kaia App
- Pathway through Pain
- Phio Engage
- selfBACK
- SupportBack

Summary of technologies (1)

Technology (Company)	ACT for PAIN (Pain Medicine Specialist Ltd)	Hinge Health Digital MSK Clinic (Hinge Health)	getUBetter (getUBetter)	Pathway through pain (Wellmind Health)
Delivery	Tablet, mobile phone or laptop			
Target conditions	Chronic pain with experience of anxiety, low mood, or other mental health problems	Recovery from LBP injuries, either acute or chronic (can also be used in wider MSK injuries)	Recovery from LBP injuries, either acute or chronic (can also be used in wider MSK injuries). Supports prevention after recovery and management of recurrent episodes	Chronic low back pain with experience of anxiety, low mood, or other mental health problems
Key features	Chronic pain psychological self-management program based on acceptance and commitment therapy (ACT)	Personalised recovery content, re-engagement algorithms to nudge participants, contact to physiotherapists and other relevant clinicians to manage treatment path	Personalised recovery content, pain pathway management including video exercise, referral, return to work support, and living well support	Pre-recorded videos and modules to support the management of chronic pain. Modules aimed to support behaviour change

MSK: musculoskeletal; AR: assessment report

Summary of technologies (2)

Technology (Company)	ACT for PAIN (Pain Medicine Specialist Ltd)	Pathway through pain (Wellmind Health)	getUBetter (getUBetter)	Hinge Health Digital MSK Clinic (Hinge Health)
NHS staff involvement	Pain specialist and psychologists who provide email advice and guidance.	Staff involved in patient care can track the progress and review patient self-assessed scores	For those who are referred by a clinician, NHS staff would be involved in registering the person with the application and supporting with safety net alerts and any necessary referrals	Little staff involvement as once referred to the app, physiotherapists and consultants available to the company would be used
Pathway placement	After other therapies have been tried and ACT is a suitable treatment	Used later in the pathway once chronic pain has been determined and mental health aspect has been identified	Can be used at any point in the pathway, ideally at the first opportunity. People can also self-refer through QR codes available through a GP	Can be used at any point in the pathway. Option for self-referral can be included in the UK if required

QR: quick response; AR: assessment report

Summary of technologies (3)

Technology (Company)	ACT for PAIN (Pain Medicine Specialist Ltd)	Pathway through pain (Wellmind Health)	getUBetter (getUBetter)	Hinge Health Digital MSK Clinic (Hinge Health)
Safety netting feature	No safety net for specific conditions (person should have been fully investigated prior to referral)	No specific safety net. Terms and conditions to use the app which include note explaining the person has had 'appropriate' investigations and is not waiting on further investigations prior to using the app. Pain must have been experienced for at least 6 months	Safety net feature in place to identify specific conditions and includes the facilitation of guiding people back into the health system where concerns of a specific condition arise	Online clinical screener used with questions to identify 'red flags'. Separate access to 1-to-1 digital appointments with clinicians is available, which can be used as a safety net feature for alarming symptoms

For further details on the technologies see section 2.1 of the AR

Summary of technologies (4)

Technology (Company)	Ascenti Reach (Ascenti)	Kaia App (Kaia Health)	PhioEngage (EQL)	selfBACK (SelfBack Consortium)	SupportBack (University of Southampton)
Target conditions	MSK pain	Chronic MSK pain	MSK pain	Non-specific LBP	Acute and persistent LBP
Summary	App-based physiotherapy service. Provides personalised exercise plan based on users' response to online assessment on symptoms, pain history, lifestyle and wellbeing.	For back pain, the app has three modules: back pain-specific education, physiotherapy and mindfulness techniques.	Provides supported self-managed care for people with MSK-related pain	selfBACK app provides participants with weekly self-management plans based on baseline questionnaire and a range of patient characteristics	SupportBack is designed to support patients to self-manage their LBP following consultation in primary care.

MSK: musculoskeletal

Condition and patient group

- Low back pain (LBP) is a common musculoskeletal (MSK) condition that affects a significant proportion of people in the UK. It is soreness or stiffness in the back, felt between the bottom of the rib cage and the top of the legs.
- The most common LBP is referred to as ‘non-specific’ which means the pain is not attributable to an underlying cause like an infection, a fracture or a disease such as cancer. Non-specific LBP can be acute (defined as lasting up to 3 months) or chronic (lasting more than 3 months)
- Non-specific LBP has a lifetime prevalence estimated to be approximately 60% (Campbell J 2013) and is the leading cause of disability worldwide and days lost from work (WHO)
- Musculoskeletal (MSK) conditions, such as LBP, are discussed in 30% of GP consultations, either as the primary or a secondary concern (NHS 2019b)
- Where MSK conditions are discussed at a GP appointment, approximately 25% of these are related to LBP (Jordan KP 2014)

GP: general practice

Current management overview

- The current care pathway for non-specific LBP is person-specific and illustrates the heterogeneous nature of non-specific LBP
- NICE's guideline on low back pain and sciatica in over 16s: assessment and management categorises the treatment for LBP into non-invasive and invasive treatments. Non-invasive treatments include non-pharmacological or pharmacological interventions and invasive treatments include non-surgical or surgical interventions.
    - Non-pharmacological interventions may include self-management advice and information, exercise, manual therapies, psychological therapy, combined physical and psychological programmes and return to work programmes
- NICE's chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain recommends acceptance and commitment therapy (ACT) or cognitive and behavioural therapy (CBT) for chronic primary pain

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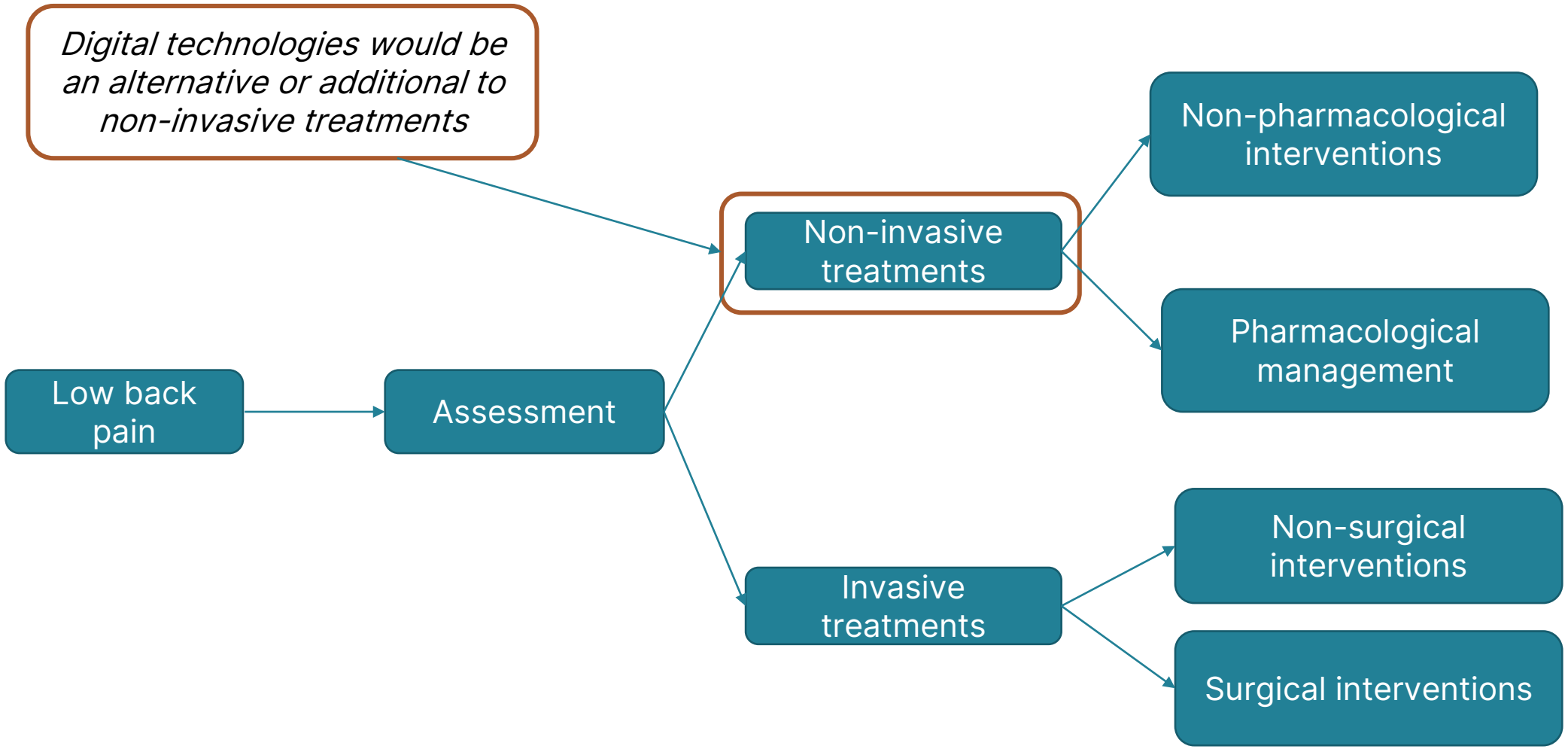
Decision problem

PICO	
Population	People aged 16 years and over with non-specific LBP that are eligible for digital technology management.
Subgroups	• people with acute non-specific LBP and people with chronic non-specific LBP
Interventions	Digital technology for LBP that provide self-management and/or psychological support
Comparator	Standard care for managing LBP
Key Outcomes	• Intermediate measures • Clinical outcomes • Patient-reported outcomes • Costs (from NHS and Personal Social Services perspective)

For full decision problem see the final scope

Care pathway



Equality and diversity

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

- LBP increases in prevalence with age and adults aged 45 years and over have an increased risk of having chronic LBP
- MSK pain disproportionately affects people from some ethnic minority backgrounds
- Digital technologies for LBP are accessed via a mobile phone, tablet, or computer. People will need regular access to a device with internet access to use the technologies. Additional support and resources may be needed for people who are unfamiliar with digital technologies or do not have access to smart devices or the internet
- Some people would benefit from digital technologies for LBP in languages other than English. Technologies should be flexible enough to address diverse language and provide additional support as needed
- People with cognitive impairment, problems with manual dexterity , learning disabilities or who have difficulty reading or understanding health-related information may need additional support to use digital technologies
- People's ethnic, religious, and cultural background may affect their views of digital interventions

Age, disability, race and religion and belief are protected characteristics under the Equality Act (2010)

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MSK: musculoskeletal

Clinical evidence summary

- 16 studies were identified as relevant and 12 were prioritised for inclusion in the review for 5 technologies: getUBetter, Hinge, Kaia, selfBACK, and SupportBack
  - 4 studies (Kaia App [n=1] and getUBetter [n=3] were deprioritised due to uncertainty about whether people with non-specific LBP were included
- No clinical studies were identified for 4 technologies: ACT for PAIN, Ascenti Reach, Pathway through Pain and PhioEngage
- Outcomes reported: function, pain self-efficacy, work, intervention adherence, engagement, treatment satisfaction, clinician satisfaction, surgical referrals, quality of life, pain, patient experience, disability, drop out, adverse events
- 47 different outcome measures were used across the 12 included studies

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Characteristics of prioritised studies

Technologies	Study design	Population	Chronic/Acute LBP	Setting
getUBetter	Retrospective case series, semi-quantitative survey (Wanless and McClellan 2019)	n=10	NR	UK
Hinge Health	RCT (Shebib 2019)	n=177	Chronic	USA
	Retrospective case series (Bailey et al 2020)	n=6,486	Chronic	USA
Kaia	RCT (Toelle et al 2019)	n=101	Mixed	Germany
	Cluster RCT (Priebe et al 2020a)	n=1,245	Acute	Germany
	Retrospective cohort study (Priebe et al 2020b)	n=333	NR	Germany
	Retrospective cohort study (Clement et al. 2018)	n=1,251	Mixed	Germany, Switzerland, UK and US
	Retrospective case series (Jain et al 2021)	n=138,337	NR	"International"
selfBACK	RCT (Sandal et al 2021)	n=461	Mixed	Denmark and Norway
	Prospective single arm trial (Sandal et al 2020)	n=51	NR	Denmark and Norway
	Prospective cohort study (Nordstoga et al 2020)	n=27	Chronic	UK and Norway
SupportBack	3 arm feasibility RCT (Geraghty et al 2018)	n=87	Mixed	UK

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NR: not reported; NHS: national health service

Outcome measures used in included studies

	Outcome measure				
1	10-item SUS	21	Health-related QoL (EQ-5D 3L).	41	RMDQ scores
2	12 Item Health Survey	22	Interest in surgery	42	Scales pain and disability
3	Acceptability	23	Modified Von Korff (MvK)	43	User activity
4	Adherence	24	NRS 11-point pain scale	44	Veterans RAND
5	Adverse events	25	Oswestry Disability Index (ODI)	45	Withdrawals
6	Average and worst LBP intensity levels in the preceding week (VAS)	26	Pain intensity (NRS 1-10)	46	Work ability index
7	BIPQ	27	Pain intensity measured by visual analogue scale (VAS)	47	WPAI scale
8	Catastrophising beliefs	28	Pain Self-Efficacy Questionnaire		
9	Clinician experience	29	Participant satisfaction		
10	Depression-Anxiety-Stress-Scale	30	PASS		
11	Dropout rate	31	Patient enablement		
12	EuroQol visual analog scale	32	Patient expectation of positive outcome (CEQ)		
13	EuroQol-5 Dimension questionnaire	33	Patient experience		
14	Fear of movement	34	Patient Health Questionnaire-Nine (PH9-Q) for depression		
15	Fear-Avoidance Beliefs Questionnaire physical activity subscale	35	Physical activity (IPAQ-SF and additional questions)		
16	Generalised Anxiety Disorder Assessment (GAD-7) for anxiety	36	Physical and mental wellbeing (VR-12)		
17	Global Perceived Effect scale	37	PSEQ		
18	Graded Chronic Pain Scale (GCPS)	38	PSFS		
19	Hannover Functional Ability Questionnaire (HFAQ)	39	Recruitment		
20	Health service cost	40	Risk of persistent disability		

Clinical evidence: EAG critique of evidence (1)

RCTS

Overall, the EAG considered the 5 RCTs to provide adequate quality evidence for the comparative effects of LBP digital technologies (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019)

- 2 RCTs were at risk of providing biased estimates of effect due to providing only per protocol analyses and being underpowered for some or all outcomes: 1 RCT evaluating SupportBack (Geraghty et al. 2018) and 1 RCT evaluating Kaia (Toelle et al. 2019)
- The remaining 3 RCTs were adequately powered with appropriate analyses
- Blinding to the identity of interventions was not feasible due to the nature of the interventions
- There is the potential risk of producing exaggerated treatment effects due to the subjective nature of the patient-reported outcomes (However, this risk cannot be avoided due to the participatory nature of these interventions)

RCT: randomised controlled trial

Clinical evidence: EAG critique of evidence (2)

Non-comparative studies

The 6 non-comparative studies were of lower quality, predominantly retrospective (4 of 6 studies), with higher proportions of missing data

Generalisability

EAG felt it was unclear if included samples are generalisable to people who would use LBP digital technologies in the UK:

- 1 study included people with acute LBP and 3 studies included people with chronic LBP
- 3 studies included a mixed population of people with acute and chronic LBP and only 1 provided subgroup data
- 5 studies did not specify whether people had acute or chronic LBP
- Definition of chronic LBP often varied from UK definition

For further details see sections 5.1 to 5.2 of AR

Clinical evidence: high level results (1)

Intermediate outcomes

Functional outcomes – 6 studies, 1 in UK, results generally positive

Pain self-efficacy – 3 studies, 1 in UK, results varied but different measures used

Work productivity – 2 studies, 0 in UK, positive results

Intervention adherence – definition and timepoints varied between all studies

- Chronic: 2 studies, 1 in UK, 32-72% adherence but definition varied,
- Mixed: 3 studies, 0 in UK, 38-78% adherence

Clinical evidence: high level results (2)

Intermediate outcomes

Engagement with technology – definitions and timepoints varied between all studies

- Chronic – 3 studies (1 in partly UK population), 75% over 12 weeks, opening the app 6.2 times a day over 4 weeks, engaging with the app for 8.36 of 12 weeks
- Acute – 1 study (not in UK), mean 25 days use over 12 weeks
- Mixed – 3 studies (0 in UK) mean 7.26 – 35 days use

Treatment satisfaction – 3 studies (1 in partly UK population), chronic and mixed, results generally positive

Clinician satisfaction – 1 study (UK), clinicians felt getUBetter enhanced the treatment pathway

Clinical evidence: high level results

Clinical outcomes

Surgical referrals – not measured directly in any studies. 2 studies (0 in UK) reported a decreased interest in surgery for chronic LBP

Patient reports outcomes

HRQOL –

- Chronic: 1 study (not in UK), positive results
- Mixed: 3 studies (0 in UK), positive and non-inferiority results

Pain – 9 studies (1 in UK), positive results for addition of tech to usual care vs usual care alone in both chronic and mixed

Oswestry Disability Index– 1 study (not in UK), chronic LBP, positive results

Patient experience – 1 study (partly in UK), mixed results

Clinical evidence: intermediate outcomes (1)

Functional outcomes – measured in 5 RCTs, 1 prospective single-arm trial across Kaia, SupportBack and selfBACK, from both primary care and mixed referrals. Positive results, studies used different measurements, 1 of the studies was in the UK

Pain self-efficacy – Measured in 1 RCT for SupportBack and 1 RCT and 1 prospective single-arm trial for selfBACK, from primary care referrals. Results varied, different measurements were used, 1 of the studies was in the UK

Work productivity – measured in 2 case series, in selfBACK and Hinge, from primary care and mixed referral settings. Both reported positive results, neither study was in UK

For further details on clinical evidence see tables 13.4 to 13.6 of the AR

Clinical evidence: intermediate outcomes (2)

Intervention adherence – 1 RCT for SupportBack and 1 retrospective case series for Hinge measured adherence to the exercise programme in people referred from primary care with chronic LBP. Results ranged from 32% to 72% but the definition of adherence also varied with the RCT requiring all 6 sessions to be completed and the case series only requiring 1 exercise to be completed in 9-12 weeks.

1 RCT for SelfBACK and 2 retrospective case series for Kaia measured adherence to the exercise programme in samples of chronic and acute LBP referred from primary and mixed referral routes. Results ranged from 38% to 78% at different timepoints (12 to 24 weeks) and with different definitions including being 'active' on the app to completing all sessions. Time ranged from 12 to 24 weeks

For further details on clinical evidence see tables 13.4 to 13.6 of the AR

Clinical evidence: intermediate outcomes (3)

Engagement with technology – 1 RCT in the USA for Hinge, 1 prospective cohort study in UK and Norway for selfBACK and 1 retrospective case series in the USA for Hinge reported activation (engagement with the technology) in different measures for people with chronic LBP, from mixed referral settings. Results included 75% over 12 weeks, opening the app 6.2 times a day over a 4-week period and engaging with the app for 8.36 of 12 weeks.

1 RCT in Germany measured app activation for Kaia in acute LBP, from a mixed referral setting. The app was used on an average of 25 days across 12 weeks.

1 RCT in Germany for Kaia, 1 retrospective case-series for Kaia in an international setting, and 1 single arm prospective trial in Denmark and Norway for selfBACK looked at activation in a mixed sample of chronic and acute LBP, from a mixed referral setting. Results varied including being used for mean of 7.26 to 35 days over study period and using the app 65 times in total over a non-specified time.

For further details on clinical evidence see tables 13.4 to 13.6 of the AR

Clinical evidence: intermediate outcomes (4)

Treatment satisfaction – 1 RCT, 1 prospective single-arm study, and 1 prospective case series measured satisfaction with treatment, from primary care and mixed referrals. All for SelfBACK, in both chronic and mixed samples. Results were generally positive.

Clinician satisfaction – 1 retrospective case series conducted in the UK for getUBetter, in a primary care setting, reported that clinicians felt that getUBetter enhanced the treatment pathway.

For further details on clinical evidence see tables 13.4 to 13.6 of the AR

Clinical evidence: clinical outcomes

Surgical referrals – The impact of the technologies on surgical referral rates were not reported by any of the included studies. But 1 RCT and 1 retrospective case series in the USA in people with chronic LBP, from a mixed referral setting, reported a decrease in interest in surgery. Both studies were in Hinge.

For further details see tables 13.7 to 13.9 of the AR

Clinical evidence: patient reported outcomes (1)

Pain – 9 studies including 5 RCTs (1 of which was in UK) (SupportBack, Kaia, Hinge), 1 prospective single-arm trial (selfBack) and 3 retrospective case series (Hinge, Kaia), from primary care and mixed referral settings, reported pain outcomes using several different tools at varying timepoints. The results suggest that the addition of digital technologies to standard care resulted in a greater improvement in pain scores regardless of duration of LBP (acute or chronic)

Health-related Quality of life (HRQoL) – Chronic LBP: 1 RCT in the USA reported that Hinge plus usual care, from a primary care setting, resulted in a significantly greater reduction in a 1-100 visual analogue scale (VAS) impact on daily life score compared to usual care: −11.8 (95% CI: −19.3, −4.3, p=0.002) at 12 weeks in the intention-to-treat population

Mixed LBP: 2 RCTs from Germany, Norway and Denmark, from a primary care setting in Kaia and selfBACK, indicated no significant effect of digital technologies on HRQoL outcomes compared to usual care. A single-arm prospective trial conducted in Denmark and Norway, in a mixed referral setting in selfBACK, reported an improvement on the EuroQol 100mm VAS of mean 9.2 (95% CI: 4.4 to 13.9) from baseline to 6 weeks

For further details see tables 13.10 to 13.11 of the AR

Clinical evidence: patient reported outcomes (2)

Oswestry Disability Index – 1 RCT (US) conducted in people with chronic LBP, from a mixed referral population reported that Hinge plus usual care resulted in a significantly greater reduction in Oswestry Disability Scores (indicating reduced impact of LBP on everyday life) compared to usual care at 12 weeks.

Patient experience – 1 prospective case series in people with chronic LBP rating selfBACK using the 10-item System Usability Scale found that at 4 weeks 16 people (UK) scored it a mean 64.7 points (SD: 21.2, range 10-95), while 10 (Norway) scored it a mean 70.5 points (SD: 20.5, range: 45-95). From 10 telephone interviews (Norway) 60% were neutral on whether the app helped with LBP management, 20% found it useful and 20% found it not useful.

For further details see tables 13.10 to 13.11 of the AR

Clinical evidence: summary

- 5 technologies had evidence (Kaia, selfBACK, SupportBack, getUBetter, ACT for PAIN)
- Broad range of outcomes: 47 outcome measures across 12 domains
- In general, there was a direction of a positive effect for digital technologies in the management of LBP
- Clinical significance of results was not explored
- Safety netting/red flag screening was not explored in any study
- AEs or patient safety data were reported in 4 studies for 3 digital technologies (Kaia app, selfBACK and SupportBack)
- EAG felt that rates of AE reported were very low and indicate that the digital technologies are plausibly safe
- Withdrawals and discontinuations were poorly and inconsistently reported. Reason for withdrawal unclear: true discontinuation from study, non-engagement with tech, or loss to follow up.

For further details see AR section 5

Clinical evidence: adverse events

Kaia app

- Retrospective case series n=138.337. 142 adverse events from n=125 participants (0.09%); increased pain n= 83 (58.4%), unpleasant sensations n=25 (17.5%), headache n=19 (13.4%), dizziness n=7 (4.9%), sleep disturbances n=4 (2.8%), and required surgery n=1 (0.7%)
- 1 German RCT n=101. 1 adverse event of disc herniation identified on routine MRI which was not considered related to intervention

selfBACK

- RCT Denmark and Norway (n=461). No adverse events reported by users of the SelfBACK App

SupportBack

- 1 UK RCT n=87. 2 hospital admissions, reasons not reported but authors reported were unlikely to be related to SupportBack

For further details on adverse events see section 6 of the AR

Clinical evidence: EAG review

- Comparative evidence indicates that digital tech may be effective as adjunct treatments to standard care in improving pain and physical function outcomes compared to standard care alone.
- Elements of standard care were not well-reported in the RCTs, introducing uncertainty
- A range of outcome measures used across trials, making comparison between digital technologies difficult.
- Evidence for other scoped outcomes, e.g. effect on use of healthcare resources, waiting time and work productivity, was limited.
- Limited evidence in acute and chronic pain sub-groups as most RCTs included patients of any LBP duration.
- No studies specifically assessed digital technologies solely from self-referrals
- Only 2 out of 12 studies were based in the UK and 2 studies included partial UK populations, limiting generalisability to UK NHS setting

For further details see section 11.1 of the AR

Issues for consideration: Clinical evidence

- Does the evidence suggest a potential benefit for the use of digital tech in addition to standard of care?
- Does the evidence suggest a potential benefit for the use of digital tech as a replacement to standard of care?
- Improvements in function and pain were relatively short term in follow-up (max 6 months), is this sufficient?
- There is limited evidence for sub-groups of acute and chronic LBP. Can these two groups be considered together? (as they often were in the evidence)
- No study evaluated safety netting/red flag screening. Should this affect potential placement in pathway?

Cost effectiveness

Digital technologies for managing low back pain

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Summary of published economic evidence

- The EAG identified 2 cost-effectiveness studies and 7 costing studies
    - The 2 cost-effectiveness studies (Lewkowicz et al. 2022 and Lewkowicz et al 2023) focused on chronic non-specific LBP and were conducted in Germany. The EAG noted that consideration should be given to the generalisability of this evidence within the UK health-care setting.
    - All 7 costing studies (Pimm et al. 2017, Geraghty et al. 2018, Pimm TJ. 2019, Optum 2022, Hinge Health 2022, Validation Institute 2023 and Health Innovation Network [Unpublished] indicated potential for cost-savings to the healthcare system although not all were specific to the UK
    - 3 of the studies were provided by Hinge Health (Optum 2022, Hinge Health 2022, Validation Institute 2023) and all had large population sizes (n=467, 8,414 and 748) and were conducted in the US
    - Not all costing studies were solely conducted in populations with non-specific LBP
    - The costing studies did not contain a full cost-effectiveness analysis but provided relevant economic evidence such as health care costs and resource use data used for the economic modelling
    - 1 of the costing studies (Health Innovation Network [Unpublished]) reported data that was used in the economic model

For further details on economic evidence see section 8 of the AR

Economic evidence – Cost effectiveness studies

Kaia App

Lewkowicz et al. (2022)

- A cost-effectiveness analysis that compared digital therapeutic care (DTC) with treatment as usual (TAU) in Germany
- The analysis simulated a cohort of patient using Markov state-transition model with 7 health states. The states included low-impact, high-impact, remission, healthy and 3 treatment states (representing treatment weeks 1 to 12)
- Data from the Kaia app study (an RCT of a digital self-management app for chronic LBP) was used to inform efficacy, cost and transition probabilities data
- The simulation found DTC was cost-effective compared to TAU, with an incremental cost-effectiveness ratio (ICER) of €5,486 per quality-adjusted life year (QALY)

Lewkowicz et al. (2023)

- This is an adapted analysis of Lewkowicz et al. (2022) and provided a probabilistic rather than a deterministic base case
- Probabilistic sensitivity analysis on the original base case results produced an ICER of €34,315 per QALY
- The large difference from the original base case ICER (€5,486 per QALY) was attributed to the very small incremental effect on QALY estimated at less than 0.01 per QALY

For further details on economic evidence see table 8.1 of the AR

Economic evidence – Costing studies (1)

getUBetter

Health Innovation Network [Unpublished]

- A mixed method evaluation that compared resource use of people with LBP who used getUBetter with resource use of non-users with LBP
- Primary data was analysed to determine health resource utilisation
- HCRU outcome data for the trial showed reduced physiotherapy and prescription referrals and fewer GP appointments.

HCRU: health care resource use

For further details on economic evidence see table 8.1 of the AR

Economic evidence – Costing studies (2)

Hinge Health

Optum 2022

- A cost and utilisation study conducted to assess the impact of the Hinge digital self-management app on health care resource use for people with chronic musculoskeletal pain in the US.
- The study adopted a retrospective cohort study design. The control group started physical therapy (back, knee, shoulder, hip, neck) during 2017-2020, whereas the Hinge Health group were enrolled on the Hinge Health App and had completed one exercise session or accessed one educational article during 2017-2020.
- The study found reductions in medical care use and associated costs between the 2 groups. The main driver of the cost savings was the reduction in hospital inpatient and outpatient appointments.

For further details on economic evidence see table 8.1 of the AR

Economic evidence – Costing studies (2)

Hinge Health

Hinge Health 2022

- A cost and utilisation study conducted to assess the impact of the Hinge digital self-management app on HCRU for people with chronic MSK pain in the US. The study adopted a retrospective cohort study design
- Participants in the intervention (Hinge Health) group completed at least one exercise session or accessed one educational article in the chronic pain program for back, knee, shoulder, hip, or neck pain between January 2020 and October 2020. The control group had a physical or occupational therapy or provider visit for back, knee, shoulder, hip, or neck pain during the same time period
- The control group of the study was a cohort of people who were not members of the Hinge Health application, where baseline characteristics were matched to those in the intervention group (n=8,414)
- The study found reductions in medical care use and associated costs between the 2 groups. The main driver of the cost savings was the reduction in claim costs primarily from reduced surgery, physical or occupational therapy and injections service use

HCRU: health care resource use

For further details on economic evidence see table 8.1 of the AR

Economic evidence – Costing studies (2)

Hinge Health

Validation Institute 2023

- A cost and utilisation study conducted to assess the impact of the Hinge Health digital self-management app on HCRU for people with chronic MSK pain in the US
- Participants were included if they used the Hinge Health programme in 2018 and could be matched to a similar non-user
- The control group of the study was a cohort of people who were not members of the Hinge Health application, where baseline characteristics were matched to those in the intervention group (n=748)
- The study found reductions in medical care use and associated costs between the 2 groups. The main driver of the cost savings was the reduction in claim costs primarily from lower use of surgery, injections and emergency room visits.

HCRU: health care resource use

For further details on economic evidence see table 8.1 of the AR

Economic evidence – Costing studies (3)

SupportBack

Geraghty et al. (2018)

- A pragmatic feasibility study that elicited the feasibility of a RCT for an internet intervention "SupportBack" for LBP.
- The study used 3 arms: usual care (1); usual care plus SupportBack (2); usual care plus SupportBack with additional physiotherapist telephone support (3)
- The study time horizon for the feasibility was 3 months, with the intervention period a 6-week time horizon, with a total of 6 sessions
- The study reported health-economic outcome measures including total primary, secondary and back pain specific costs. The study showed the health economic cost outcome data may reduce healthcare resource use for LBP
- The study concluded that it was feasible to conduct a future RCT to determine the clinical and cost-effectiveness of an internet intervention (SupportBack) for people with LBP

RCT: randomised controlled trial

Further details about the economic evidence is in the AR pages 54 - 63

Economic evidence – Costing studies

Pathway through Pain

Pimm et al. (2017)

- A poster highlighting the results from a pre/post-test study of the digital pain management pathway (PMP) “pathway through pain (PTP)” versus TAU
- Study included 1,062 with chronic pain referred by physiotherapists between 2012 and 2016. Final analysis on healthcare costs were for a lower number n=90 for TAU and n=100 for intervention
- Cost difference between the pre-intervention and post intervention average cost for the TAU group was £127.01 and -£414.77 for the intervention group

Pimm TJ (2019)

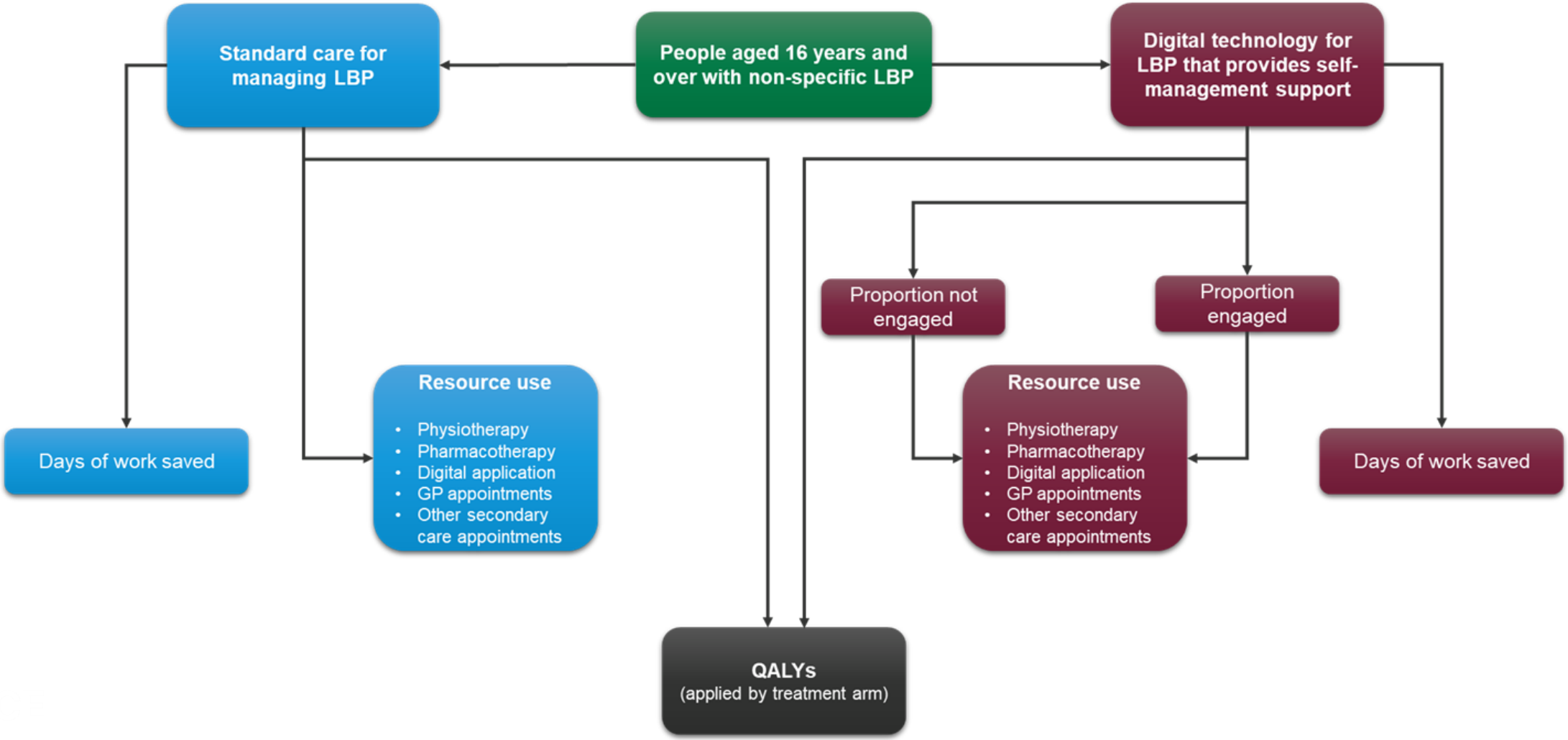
- A pre-post observational study comparing the difference in health care usage between individuals who engaged in a digital PMP “PTP” and those who did not
- 837 participants with chronic pain were recruited via physiotherapy referral. 12% were unsuitable for PTP, of the suitable participants 59% accessed PTP (engaged group) and 41% did not access PTP (non-engagers)
- Results for difference in costs related to health care resource use (HCRU) for the year before referral and the year after showed reduced HCRU costs for the engaged and increased HCRU costs for the non-engaged group

TAU: treatment as usual

For further details on economic evidence see table 8.1 of the AR

Economic model structure

- The EAG developed a simple cost-utility model designed to capture the potential benefit that could be provided from these technologies over a 1-year time horizon



Economic model structure

The model is an initial exploration of the economic impact of digital technologies that provide self-management support alongside standard care for the treatment of non-specific LBP. For the model, the EAG:

- Estimated resource use across the different treatment arms and applied costs to the different resource use
- Used quality-adjusted life year (QALY) figures based on previous studies and valuated cost effectiveness using threshold of £20,000 per QALY
- Did not consider mortality given the short time horizon and in line with the outcomes captured in the evidence
- Used 1-year time horizon because long-term benefit of treatment was very uncertain (maximum follow-up from included clinical studies was 9 months).

The EAG did not include ACT for PAIN in the economic model because it is the only technology offering psychological therapy, there is very weak evidence about the cost-effectiveness of ACT in the UK, and there was no evidence provided by the company that pertained to the effectiveness of digital ACT specifically

For further details on the model structure see section 8.2.2 of the AR

Economic model assumptions

The model relies on several assumptions and has some limitations:

- Any safety feature built into the technology is assumed to be 100% effective
- Costs of the technologies can be scaled down to a per person cost
- Training and implementation costs are excluded in the base case as it's unclear what resource use will be required
- Some of the data used in the model is not exclusive to non-specific LBP population
- Outcomes associated with preventing chronic pain at the acute phase are not fully captured
- Long-term outcomes of treatment are not captured as the model uses a 1-year time horizon due to short follow-up in the available clinical evidence. Also, people are at risk of relapse and are likely to seek further treatment, particularly those with chronic LBP
- The impact of waiting time is not fully captured in order to avoid double counting of the potential benefits
- Healthcare appointments and overall prescriptions are scaled in the same way regardless of chronic or acute pain.
- The specific place of the digital technologies in the care pathway isn't captured

Further details about these assumptions see table 8.2 of the AR

Economic model – Cost and resource parameters summary (1)

- Model inputs were derived via clinical correspondence and company evidence submissions. Inputs from 3 digital technologies, Hinge, getUBetter and selfBACK, were used to inform all parameters in the economic model (excluding cost of technologies)
- Where possible, the range of values from the company evidence submissions were used as uncertainty intervals for sensitivity analysis
- Costs were derived from company evidence submissions, PSSRU (Jones 2022), BNF and the National Cost Collection for 2022
- The base case average cost per person per year for the digital technologies (where costs were available) to support non-specific LBP is £199.21. Costs were available for getUBetter, Hinge, Pathway through Pain, selfBACK and SupportBack

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PSSRU – Personal Social Services Research Unit; BNF – British National Formulary

Further details see section 8.2.4 of the AR

Economic model – Cost and resource parameters summary (2)

- The proportion engaged with treatment was derived from Bailey et al. (2020) which reported on Hinge. The study measured engagement as the proportion of people who completed the digital care program. Other company evidence submissions measured engagement as people logging on to or downloading the app.
- EQ-5D and EQ-VAS were included in the model to elicit utility scores in association with LBP at baseline, 3 months, 6 months, 9 months and 1 year.
- The EAG analysed input such as general population earnings and number of days missed due to LBP to estimate the cost of absenteeism due to LBP

Further details see section 8.2.4 of the AR

Economic model - Costs & resource parameters

Parameter	Value	Study	EAG's comments
Population model inputs			
Prevalence of LBP	5.87%	Jordan KP (2014)	Prevalence of LBP in England per 10,000 people is reported as 587.
Proportion of LBP that is acute	42.1%	Sandal et al. (2021)	1-proportion of LBP that is chronic (1-0.579) = 0.421
Proportion of LBP that is chronic	57.9%	Sandal et al. (2021)	Table 1. Of all patients with LBP, 57.92% (267/461) had a current pain episode of >12 weeks. RCT including 461 participants in Denmark and Norway.
Efficacy inputs – proportion engaged			
Digital technologies for non-specific LBP	72.3%	Bailey et al. (2020)	Table 2. 'Completers' proportion of total back pain population, 4,676 / 6,468 = 72.29% The paper includes participants with chronic knee or back pain, not solely LBP. The EAG assumed the proportion engaged is equal between both people with chronic and acute.
Return to work inputs – general population earnings			
Annual earnings of employed adults	£27,756	Office for National Statistics (2022)	Median gross annual earnings from ONSE ASHE 1997 to 2017 selected estimates.
Daily earning for employed adults	£106	Calculated	Calculated by the annual earnings of employed adults / number of working days per year. £27,756 / 260.893

For further details see table 8.3 – 8.17 of the AR

Economic model – Health state utilities

Parameter	EQ-5D		EQ-VAS	
	Standard care	Intervention	Standard care	Intervention
3 months	0.74	0.76	0.71	0.71
9 months	0.76	0.78	0.72	0.73
Source	Sandal et al. (2021)			

- The EAG assumed acute and chronic take the same value for each respective time period
- For the model, the EAG scaled up these data to one year by weighing the quality-adjusted life years (QALYs) by the number of timepoints recorded

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For further details see table 8.15 – 8.16 of the AR

Base case results

	Digital technologies for non-specific LBP*	Standard care	Incremental
Deterministic base case results			
Cost per person	£560	£644	-£84
QALYs per person	0.76	0.75	0.01
Incremental cost effectiveness ratio (ICER)			Dominant
Net monetary benefit (NMB)			£373
Net health benefit (NHB)			0.02
Cost breakdown per person			
Technology costs	£199	£0	£199
Primary care	£265	£484	-£218
Secondary care	£50	£89	-£38
Medications	£45	£72	-£27

* Alongside standard care; QALY: quality adjusted life years

Scenario analyses

The EAG did a range of scenario analysis given the potential variation in digital technologies for managing LBP such as pricing and the uncertainty in input values due to limited evidence

- All but 1 scenario were plausibly cost effective at £20,000 per QALY threshold. This scenario changed the direction of the base case result in the chronic pain subgroup only
- 5 scenarios indicated that the digital technologies used alongside standard care would not be cost saving. One of which includes when using the highest-cost digital technology
- The highest-cost digital technologies were still cost-effective at a £20,000 per QALY threshold
- Other scenarios suggested that when the resource use is scaled down to 1-month, digital technologies may not be cost-saving when considering acute pain only
- There was little difference in the quality-of-life impact between people with acute and chronic pain subgroups due to the limited data available to stratify by these different types of pain
- If the highest-cost device is used for a subgroup of people with chronic pain, the cost-effectiveness results would be above a £20,000 per QALY threshold and resulted in an NMB of -£100

QALY: quality adjusted life years; NMB: net monetary benefit

For further details see section 8.3.1 of the AR

Sensitivity analysis

The EAG conducted a few targeted sensitivity analyses to explore the uncertainty of key parameters in the model

- One-way sensitivity analysis suggests the following parameters are the key drivers of cost-effectiveness in the model
    - Cost of the digital technologies
    - Relative difference in HRQoL between the digital technologies and standard care
    - Proportion engaged with the digital technologies for both acute and chronic pain
    - Reduction in physiotherapy referrals and the number of appointments after being referred
- Economic justifiable price (EJP) analysis showed that the highest price of the digital technologies while still leading to cost-savings was approximately £280 per person
    - Approximate EJP per person for acute and chronic subgroup specifically was £200 and £330 respectively
- The probabilistic sensitivity analysis (PSA) indicated similar results to the deterministic base case

EAG: economic assessment group; HRQoL: health-related quality of life

For further details see pages 93 – 95 of the AR

ACT for PAIN and its potential impact

- The EAG noted that ACT for PAIN is likely to require different resource use compared to the studies used to populate the model given that it is the sole psychological intervention out of the included technologies
- The company did not submit any evidence which supports the use of their technology in particular
- The company submitted evidence for the use of acceptance and commitment (ACT) therapy in general. The EAG did not identify any studies using ACT for PAIN
- To estimate the potential impact of ACT for PAIN, clinical feedback suggested that ACT is likely to be used instead of other psychological therapies, such as cognitive behavioural therapy (CBT)
- There's limited evidence in the UK regarding the cost of ACT
- The EAG used CBT cost as a proxy to calculate the average cost of ACT based on clinical feedback that both costs would be similar. They noted that ACT may cost more given it is an intensive treatment
- EAG noted that using the calculated proxy cost for ACT, ACT for PAIN is more expensive. However, it has the potential to cover reoccurrence as the cost is paid upfront, rather than as a subscription which may not be the case for digital forms of CBT

EAG: economic assessment group; ACT: acceptance and commitment therapy;
CBT: cognitive behavioural therapy

Clinical and economic evidence base for ACT

ACT is recommended by NICE to manage chronic primary pain NICE's chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain

The EAG noted that the evidence for the NICE guideline included 2 clinical and 1 economic study. Both clinical studies were considered as low- or very low-quality evidence with a very high risk of bias, while the economic study included was from the perspective of Spain, which is not expected to be generalisable to the UK

Findings from a recent systematic review and meta-analysis (Lia L 2023) suggested that ACT:

- Improved pain intensity and psychological outcomes compared with standard care
- Had a larger impact on physical function than pain intensity
- Was estimated to lead to statistically significant improvements in quality of life
- Had a significantly smaller effect when delivered digitally when compared with face-to-face on pain intensity and physical function.

ACT: acceptance and commitment therapy

For further details see section 8.4 of the AR

ACT for PAIN – exploratory analysis

The EAG provide crude estimate for cost saving and effectiveness estimate for ACT for PAIN

- In order to be cost saving compared to other ACT or CBT, ACT for PAIN would likely have to lead to approximately a £522 reduction in healthcare costs such as reducing primary care and secondary care visits, medications, and physiotherapy
- The estimated benefit to be cost effective at £20,000 per QALY would be:
  - An increase of at least >0.03 QALYs per person, assuming no difference to other healthcare costs.
  - An increase of 0.02 QALYs per person and at least a £125 reduction per person in other healthcare costs.
  - An increase of 0.01 QALYs per person and at least £325 reduction per person in healthcare costs.

The EAG notes that given current evidence suggests that digital ACT may be less effective, the impact of ACT for PAIN is uncertain and further evaluation should be considered on ACT more widely

ACT: acceptance and commitment therapy; CBT: cognitive behavioural therapy; QALY: quality adjusted life years

For further details see section 8.4 of the AR

Gap analysis

- No clinical evidence was identified for Ascenti Reach, ACT for PAIN, Pathway through Pain or PhioEngage. There was economic evidence for Pathway through Pain
- Comparative evidence was available for some key outcomes, e.g. pain and functional outcomes but a range of outcome measures were used making comparison across technologies difficult. Using common outcome measures would facilitate the comparison of different technologies.
- Other outcomes were not well-reported, including work productivity and patient experience and satisfaction.
- EAG recommend that systematic collection of adverse data should be considered
- The evidence base was scarce for the effect of digital technologies on referral rates for other services such as imaging, physiotherapy or surgical referrals and emergency department attendances

NICE

AE: adverse event

Key economic considerations

- Digital technologies with usual care has a potential cost saving of £84 per person and 0.01 QALY gain but EAG warns results are highly uncertain based on naïve and limited data
- There is limited economic evidence and neither of the cost effectiveness evaluations were specific to the UK
- There is uncertainty of the expected impact on healthcare resource use, true HRQoL impact and long-term outcomes
- Studies with a different population were used to populate the model
- The key drivers of the economic results were, technology cost, relative difference in HRQoL, proportions engaged with the technologies, physiotherapy referrals and number or appointments

HRQoL: health related quality of life

Gap analysis

- There was insufficient evidence to consider whether the variation in components used across digital technologies impacted outcomes (e.g. sensor-guided exercise and AI-powered guidance-tailoring).

- No evidence was found for the following outcome measures in any technology:

    - change in number of appointments needed
    - time to recovery
    - patient choice or preference
    - number of physiotherapy referrals
    - treatment waiting list volume and times
    - self-removal from waiting list
    - reduced pharmacological management
    - reoccurrence of LBP
    - reduced imaging referrals
    - reduced attendances at emergency department
    - musculoskeletal health questionnaire

Gap analysis – intermediate outcomes

Outcomes	Hinge	Kaia app	selfBACK	SupportBack	getUBetter
Pain self-efficacy	Nil RED	Nil RED	1 RCT, non-UK 1 prospective single-arm trial, non-UK AMBER	1 UK feasibility RCT AMBER	Nil RED
Work productivity	1 retrospective case series, non-UK RED	1 retrospective cohort study, non-UK RED	1 prospective single-arm trial, non-UK RED	Nil RED	Nil RED
Intervention adherence	1 retrospective case series, non-UK RED	2 retrospective case series, partial UK AMBER	1 RCT, non-UK AMBER	1 UK feasibility RCT AMBER	No studies RED
Activation measures	1 RCT, non-UK 1 retrospective cohort study, non-UK AMBER	2 RCTs, non-UK 1 retrospective case series, non-UK AMBER	1 prospective single-arm trial, non-UK 1 prospective case series, partial UK population AMBER	Nil RED	Nil RED
Treatment satisfaction and engagement (patient opinion)	Nil RED	Nil RED	1 RCT, non-UK 1 prospective case series, partial UK population 1 prospective single-arm trial, non-UK AMBER	Nil RED	1 retrospective case series UK population RED
Clinician satisfaction	Nil RED	Nil RED	Nil RED	Nil RED	1 retrospective case series in UK RED

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RED: no comparative evidence for the scoped population; **AMBER:** weak comparative evidence for the scoped population, **GREEN:** robust comparative evidence for the scoped population

Gap analysis – AEs, drop out and clinical outcomes

Outcomes	Hinge	Kaia app	selfBACK	SupportBack	getUBetter
Intervention-related adverse effect	Nil RED	1 RCT, non-UK 1 retrospective case series, non-UK AMBER	1 RCT, non-UK AMBER	1 UK feasibility RCT AMBER	Nil RED
Withdrawals/ discontinuations	1 RCT, non-UK 1 retrospective case series non-UK AMBER	2 RCTs, non-UK 1 retrospective case series, partial UK AMBER	1 RCT, non-UK 1 prospective single-arm trial, non-UK 1 prospective case series, partial UK AMBER	1 UK feasibility RCT AMBER	No studies RED
Surgical referrals	Proxy outcome, 1 RCT, non-UK 1 retrospective case series, non-UK RED	Nil RED	Nil RED	Nil RED	Nil RED

NICE

RED: no comparative evidence for the scoped population; **AMBER:** weak comparative evidence for the scoped population, **GREEN:** robust comparative evidence for the scoped population

Gap analysis – patient reported outcomes

Outcomes	Hinge	Kaia app	selfBACK	SupportBack	getUBetter
Functional outcomes	1 RCT non-UK AMBER	2 RCTs, non-UK AMBER	1 RCT, non-UK 1 prospective single-arm trial AMBER	1 UK feasibility RCT AMBER	Nil RED
Pain	1 RCT non-UK 1 retrospective case series, non-UK AMBER	2 RCTs, non-UK 2 retrospective case series, partial UK population AMBER	1 RCT non-UK 1 prospective single-arm trial AMBER	1 UK feasibility RCT AMBER	Nil RED
HRQoL	1 RCT, non-UK AMBER	1 RCT, non-UK AMBER	1 RCT, non-UK 1 prospective single-arm trial AMBER	Nil RED	Nil RED
Back specific disability score (Oswestry Disability Index for LBP)	1 RCT, non-UK AMBER	Nil RED	Nil RED	Nil RED	Nil RED
Patient experience	Nil RED	Nil RED	1 prospective case series RED	Nil RED	Nil RED

NICE

RED: no comparative evidence for the scoped population; **AMBER:** weak comparative evidence for the scoped population, **GREEN:** robust comparative evidence for the scoped population

Key considerations: Gap analysis

•There is some available evidence to suggest positive impact on outcomes when used alongside standard care but limited comparative evidence for subgroups and follow up. Evidence is limited on psychological management

•No evidence was identified that suggested the addition of digital technologies reduces patient safety

•Agreement is needed on quality-of-life measure. Is the EQ-5D-3L suitable for evaluating quality of life differences?

•Which pain score is most clinically useful and appropriate for data collection?

•Evidence should be gathered on people's pain score over time and related to outcomes such as resource use and quality of life

•Evidence is limited on the impact digital technologies may have on healthcare resource use

Issues for consideration: Clinical evidence

- Does the evidence suggest a potential benefit for the use of digital tech in addition to standard of care?
- Does the evidence suggest a potential benefit for the use of digital tech as a replacement to standard of care?
- Improvements in function and pain were relatively short term in follow-up (max 6 months), is this sufficient?
- There is limited evidence for sub-groups of acute and chronic LBP. Can these two groups be considered together? (as they often were in the evidence)
- No study evaluated safety netting/red flag screening. Should this affect potential placement in pathway?

Issues for consideration: Economic evidence

- Digital technologies with usual care has a potential cost saving of £84 per person and 0.01 QALY gain but EAG warns results are highly uncertain based on naïve and limited data
- There is limited economic evidence and neither of the cost effectiveness evaluations were specific to the UK
- There is uncertainty of the expected impact on healthcare resource use, true HRQoL impact and long-term outcomes
- Studies with a different population were used to populate the model
- The key drivers of the economic results were, technology cost, relative difference in HRQoL, proportions engaged with the technologies, physiotherapy referrals and number or appointments

HRQoL: health related quality of life

NICE National Institute for Health and Care Excellence

Thank you.

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Possible recommendations

Conditionally recommended for use while further evidence is generated

- Likely that the technology will solve the unmet need and it is acceptable for the technology to be used in practice while further evidence is generated

Recommended only in a research context

- Uncertain if the technology has the potential to solve the unmet need, or it is not acceptable to be widely used in practice while further evidence is generated

Not recommended for use

- Unlikely that a technology has the potential to meet the unmet need, or where there are concerns about the potential harms associated with using the technology even in a research context

Deprioritised studies

- 4 studies were deprioritised due to uncertainty about whether people with non-specific LBP were included
- 1 Kaia app pilot RCT
- 3 retrospective studies provided by getUBetter Ltd

- getUBetter Ltd confirmed that the study populations of the 3 retrospective case studies included people with specific LBP
- No clarification was received from Kaia Health

NICE National Institute for Health and Care Excellence