NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Early Value Assessment

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

External Assessment Group report

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Purpose of the assessment report

The purpose of this External assessment group (EAG) report is to review the evidence currently available for included technologies and advise what further evidence should be collected to help inform decisions on whether the technologies should be widely adopted in the NHS. The report may also include additional analysis of the submitted evidence or new clinical and/or economic evidence. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Medical Technologies Advisory Committee when it is making decisions about the early value assessment.

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> <u>employees.</u>

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Responsibly for report

The views expressed in report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

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Abbreviations

| Term | Definition | |
|----------|---|--|
| A&E | Accident and emergency | |
| ACT | Acceptance and commitment therapy | |
| AE | Adverse event | |
| AQoL-6D | Assessment of quality of life – 6D scale | |
| BIPQ | Brief illness perception questionnaire | |
| BL | Baseline | |
| BMI | Body-mass index | |
| BNF | British National Formulary | |
| СВР | Chronic back pain | |
| СВТ | Cognitive behavioural therapy | |
| CCG | Clinical Commissioning Group | |
| CEQ | Communication effectiveness questionnaire | |
| CI | Confidence interval | |
| СТ | Clinical trial | |
| DC | Day case | |
| DHSC | Department of Health and Social Care | |
| DHT | Digital health technology | |
| DSA | Deterministic sensitivity analysis | |
| DTC | Digital therapeutic care | |
| EAG | External assessment group | |
| ED | Emergency department | |
| EJP | Economically justifiable price | |
| EQ-5D | EuroQol 5 dimension | |
| EQ-5D 3L | EuroQol 5-dimension 3 level | |
| EQ-VAS | EuroQol visual analogue scale | |
| F2F | Face-to-face | |
| FABQ | Fear avoidance belief questionnaire | |
| FFS | Free-for-service | |
| GAD-7 | Generalised anxiety disorder assessment | |
| GBP | Great British pound | |
| GCPS | Graded chronic pain scale | |
| HAM-D | Hamilton depression rating scale | |
| НСР | Health care practitioner | |
| | | |

| Term | Definition | |
|-----------|--|--|
| HCRU | Health care resource utilisation | |
| HFAQ | Hannover functional ability questionnaire | |
| HRQoL | Health-related quality of life | |
| HQ | Health questionnaire | |
| HSDR | Health and social care delivery research | |
| ICER | Incremental cost-effectiveness ratio | |
| ICS | Integrated care system | |
| ICUR | Incremental cost-utility ratio | |
| IMI | Internet and mobile-based intervention | |
| IPAQ-SF | International physical activity questionnaire – short form | |
| IPQ | Illness perception questionnaire | |
| ITT | Intention to treat | |
| LBP | Low back pain | |
| MAUDE | Manufacturer and User Facility Device Experience | |
| MHRA | Medicines & Healthcare products Regulatory Agency | |
| MSK | Musculoskeletal | |
| MTEP | Medical Technologies Evaluation Programme | |
| MvK | Modified Von Korff | |
| NA | Not applicable | |
| NES | Non-elective short stay | |
| NG193 | NICE guideline 193 | |
| NHB | Net health benefit | |
| NIHR | National Institute for Health and Care Research | |
| NMB | Net monetary benefit | |
| NR | Not reported | |
| NRS | Numerical rating scale | |
| NSAID | Non-steroidal anti-inflammatory drug | |
| ODI | Oswestry Disability Index 33 | |
| ONS | Office of National Statistics | |
| ONSE ASHE | Office for National Statistics Annual Survey for Houses and Earnings | |
| OR | Odds ratio | |
| PESQ | Pain self-efficacy questionnaire | |
| PASS | Patient acceptable symptom state | |
| PH9-Q | Patient health Questionnaire 9 | |
| | | |

| Term | Definition | |
|--------|--|--|
| PMP | Pain management program | |
| РМРМ | Per member per month | |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses | |
| PSA | Probabilistic sensitivity analysis | |
| PSEQ | Pain self-efficacy questionnaire | |
| PSFS | Patient specific functional scale | |
| PSSRU | Personal Social Services Research Unit | |
| QALY | Quality-adjusted life year | |
| QoL | Quality of life | |
| QR | Quick response | |
| QUORUM | Quality of Reporting of Meta-Analyses | |
| RCT | Randomised controlled trial | |
| RMDQ | Roland-Morris disability questionnaire | |
| SD | Standard deviation | |
| SUS | System usability scale | |
| TAU | Treatment as usual | |
| TENS | Transcutaneous electronic nerve stimulator | |
| VAS | Visual analogue scale | |
| Vs | Versus | |

Executive summary

Background

Low back pain (LBP) is soreness or stiffness in the back, felt between the bottom of the rib cage and the top of the legs. Non-specific LBP can be described as having no identifiable structural cause or pathoanatomical abnormality. The target population for this assessment are people aged 16 and over with non-specific LBP who are eligible for digital technology management. This early value assessment summarises the clinical and economic evidence for digital technologies for non-specific LBP, while also outlining the current evidence gaps for these technologies.

Quality and relevance of the clinical evidence

The EAG considered evidence for 5 of the scoped technologies from 5 randomised controlled trials (RCTs), 1 prospective single arm trial, 1 prospective case series and 5 retrospective case series. Overall, the evidence base suggests that digital technologies alongside standard care may result in greater improvement of pain and physical function than standard care alone in people with non-specific LBP. Evidence on the other scoped outcomes was limited. The EAG had concerns regarding the generalisability of the identified evidence to the UK NHS setting, the heterogeneity of outcome measures, and lack of clear reporting of the content of standard care.

Quality and relevance of the economic evidence

The economic analysis conducted by the EAG was a cost-utility model designed to capture the potential benefit that could be provided from the digital technologies over a 1-year time horizon. The analysis found that the incorporation of digital technologies to support the management of non-specific LBP into the NHS has the potential to be cost saving and improve quality of life. However, the results are based on naïve and limited data with a high level of uncertainty, particularly due to the heterogeneity of the digital technologies and the placement of each in the care pathway. Model inputs were primarily sourced though clinical advice, company-provided detail and 1 conducted mixed-population economic study.

Evidence gap analysis

Future evidence generation should focus on addressing the key components of the value proposition of digital technologies for managing non-specific LBP. This includes:

- Use of common and applicable outcome measures in the evidence base to facilitate comparison of the different technologies to the current care pathway.
- Evidence generation on the differences in healthcare resource use from using digital technologies alongside standard care.

Greater reporting of patient characteristics, including the type of back pain, the number of people with acute or chronic LBP, pain severity at baseline, the placement of the technology in the care pathway, and the healthcare resource use will all expand the evidence base. RCTs are the gold standard for answering this research question. However, since digital technologies have already been implemented by the NHS to support management of non-specific LBP, comparative data could be obtained through prospective collection of relevant outcomes in controlled cohort studies or non-RCTs.

The EAG recommends that future evaluations should not look to treat all digital technologies for managing non-specific LBP as homogenous healthcare technologies. Any future economic modelling should be designed to be flexible enough to be adapted to all non-specific LBP digital technologies, ideally using a cohort state transition model.

1 Decision problem

The decision problem is described in <u>the scope</u>.

| Table 1.1: Summary | y of decision problem | ì |
|--------------------|-----------------------|---|
|--------------------|-----------------------|---|

| Decision problem | Scope | EAG comment |
|-----------------------|--|---|
| Population | People aged 16 years and over with non-specific Low back pain (LBP) that are eligible for digital technology management. Non-specific defined as people with LBP not caused by: specific causes of LBP for example cancer, infection, trauma, or inflammatory disease such as spondyloarthritis sciatica pain associated with nerve root entrapment Subgroups: people with acute non-specific LBP | No change. |
| | and people with chronic non-specific LBP. | |
| Intervention | Digital technology for LBP that provide self- management and/or psychological support. This includes: ACT for PAIN Ascenti Reach getUBetter Hinge Health Digital MSK Clinic Kaia app Pathway through Pain selfBACK SupportBack | Due to the volume of literature identified for similar non-scoped interventions, this EVA was limited to studies evaluating any 1 of the 8 listed interventions plus PhioEngage (EQL Ltd). |
| Comparator(s) | Standard care for managing LBP | No change. |
| Healthcare setting | Outpatient clinics, primary care, community care or home-based care | Studies categorised according to whether patients were referred from primary care settings, self-referral settings or mixed/unclear settings. |

| Decision problem | Scope | EAG comment |
|---------------------|--|--|
| Outcomes | As listed in the <u>final scope</u>: Intermediate measures Clinical outcomes Patient-reported outcomes Costs (from NHS and Personal Social Services perspective) | Outcomes on referral rates for other services (imaging, physiotherapy or surgical referrals and emergency department attendances) were not well-reported. |
| Cost analysis | Costs will be considered from an NHS and Personal Social Services perspective. Costs for consideration may include: Cost of technologies, including subscription costs Primary care and secondary care resource use, such as GP appointments, physiotherapy referrals and other healthcare appointments In scenario analysis, a wider societal perspective may also be included to include work productivity/return to full activity outcomes | No change. |
| Subgroups | Analysis may consider differences between acute LBP and chronic LBP, if there is sufficient evidence. | Limited evidence was available on digital technologies in acute and chronic pain populations specifically, as most comparative studies included patients of any LBP duration. |

Key: EAG – external assessment group, LBP – Low back pain.

2 Overview of the technology

Included in this early value assessment are digital technologies that provide selfmanagement and/or psychological support for the treatment of non-specific LBP in people aged 16 and over who are eligible for digital technology management. Nonspecific LBP is defined further in section 3. The digital technologies can be used by those with either acute pain or chronic pain. They may support the management of LBP through different points in the care pathway, or through different treatment mechanisms. The aim of the digital technologies is to provide rapid access to specialist advice and guidance, giving individuals the flexibility to work through recommendations in their own time. The support provided by the digital technologies could include information, education, advice, psychological therapies, or further signposting of resources. In turn, this may reduce primary and secondary care resource use, while also supporting quicker recovery. Technologies may also have a 'safety net' feature, designed to capture people who may have a specific cause for their LBP, which in turn may require a different treatment pathway. The importance of this is likely to depend on factors such as where the technology is placed in the pathway.

Technologies considered should ideally have support from healthcare professionals such as physiotherapists, pain management specialists or clinical psychologists. Any technologies included should have regulatory approval or be actively working towards regulatory approval, DTAC and CE or UKCA mark where required, and be available for use in the NHS.

2.1 Included technologies

In total, 9 digital technologies to support the self-management of non-specific LBP were identified as relevant to the assessment. 8 were included in the NICE Scope, while PhioEngage (EQL Ltd) was identified at a later date and considered relevant for the evaluation. Details relevant to this early value assessment are summarised in Table 2.1. Further details on the original 8 technologies are detailed in the NICE Scope.

| Technology (Company) | Regulatory Status | EAG Summary |
|---|---|--|
| ACT for PAIN (Pain Medicine Specialist Ltd) | Does not have either DTAC or CE/UKCA mark. Company submission does not indicate any plans to seek regulatory approval. | Delivery: Tablet, mobile phone, or laptop. Target condition: Chronic 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). NHS staff involvement: Pain specialist and psychologists who provide email advice and guidance. |

| Table 2 | 2.1: | Included | techno | loaies |
|---------|------|----------|--------|--------|
|---------|------|----------|--------|--------|

| Technology (Company) | Regulatory Status | EAG Summary |
|--|---|---|
| | | Pathway placement : After other therapies have been tried and ACT is a suitable treatment. |
| | | Safety net to identify specific condition: Person should have been fully investigated prior to referral. No safety net for specific conditions. |
| | | Current use in the NHS: |
| Ascenti Reach (Ascenti) | The company did not provide information to NICE. | |
| getUBetter (getUBetter Ltd) | The device is registered as a class 1a medical device under CE marking. No mention of UKCA mark. | Delivery: Tablet, mobile phone, or laptop. Target condition: 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. |
| | DTAC: accredited | Key features: Personalised recovery content, pain pathway management including video exercise, referral, return to work support, and living well support. |
| | | NHS staff involvement: 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. |
| | | Pathway placement : 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. |
| | | Safety net to identify specific condition: 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. |
| | | Current use in the NHS: |
| Hinge Health Digital MSK Clinic 'Hinge' (Hinge Health) | The device is not yet CE or UKCA marked. Process for gaining approval is underway. | Delivery: Tablet, mobile phone, or laptop. |

| Technology (Company) | Regulatory Status | EAG Summary |
|--|---|---|
| | DTAC: not yet accredited but beginning to seek | Target condition: Recovery from LBP injuries, either acute or chronic (can also be used in wider MSK injuries). |
| | DTAC accreditation. | Key features: Personalised recovery content, re- engagement algorithms to nudge participants, contact to physiotherapists and other relevant clinicians to manage treatment path. Note: all features of Hinge may not be recommended as part of clinical practice in the UK, such as the use chiropractic techniques. |
| | | NHS staff involvement: Little staff involvement as once referred to the app, physiotherapists and consultants available to the company would be used. |
| | | Pathway placement : Can be used at any point in the pathway. Option for self-referral can be included in the UK if required. |
| | | Safety net to identify specific condition: 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. |
| | | Current use in the NHS: |
| Kaia app (Kaia Health) | The company did not provide information to NICE. | There are multiple iterations of applications produced by Kaia Health. One which is for all pain, and one which is solely for back pain. Given the decision problem, evidence for the Kaia app is focused on the iteration for back pain. |
| Pathway through Pain (Wellmind Health) | The device is registered as a class 1a medical device under CE marking. UKCA mark is in the process of being | Delivery: Tablet, mobile phone, or laptop. Target condition: Chronic low back pain with experience of anxiety, low mood, or other mental health problems. |
| | acquired, considered a class 1 medical device. | Key features: Pre-recorded videos and modules to support the management of chronic pain. Modules aimed to support behaviour change. |
| | DTAC: accredited | NHS staff involvement: Staff involved in patient care can track the progress and review patient self-assessed scores. |

| Technology (Company) | Regulatory Status | EAG Summary |
|---|--|---|
| | | Pathway placement : used later in the pathway once chronic pain has been determined and mental health aspect has been identified. |
| | | Safety net to identify specific condition: 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. |
| PhioEngage (EQL Ltd) | The company did not provide information to NICE. | |
| selfBACK (SelfBACK Consortium) | The company did not provide information to NICE. | |
| SupportBack (University of Southampton) | The company did not provide information to NICE. | In order to use SupportBack, individuals would have to be triaged through the application STarT Back, a clinical decision triage tool. Therefore, these 2 applications are likely to be linked when considering the effectiveness of SupportBack. |

Key: ACT – Acceptance and commitment therapy, ICS – Integrated care system, LBP – Low back pain, MSK – Musculoskeletal, QR – Quick response.

3 Clinical context

LBP is soreness or stiffness in the back, felt between the bottom of the rib cage and the top of the legs. Non-specific LBP can be described as having no identifiable structural cause or pathoanatomical abnormality (Mayer C 2016). This differs from LBP with an identifiable cause, such as discogenic LBP, facet joint pain, or other specific conditions.

The target population for this assessment are people aged 16 and over with nonspecific LBP who are eligible for digital technology management. Non-specific LBP has a lifetime prevalence estimated to be approximately 60% (Campbell J 2013). It is a leading cause of disability worldwide and days lost from work (Chenot JF 2017). This early value assessment will consider both acute (defined as lasting up to 3 months) or chronic (lasting more than 3 months) non-specific LBP.

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). However, research suggests self-management is a key treatment strategy for non-specific LBP. Innovative technologies that promote self-management of non-specific LBP or provide psychological treatment may have potential to reduce NHS resource use and improve people's recovery and management of non-specific LBP. GP appointments, physiotherapy sessions, pain management programs (PMP)'s, and acceptance and commitment therapy (ACT) are a non-exhaustive list of NHS resources where usage could potentially be reduced. These resources can be face-to-face or online. Furthermore, technologies that support self-management or provide psychological treatment align with existing NICE guidance for LBP (National Institute for Health and Care Excellence 2020b). Hence, these technologies take steps towards a more patient-led treatment of non-specific LBP.

The current care pathway for non-specific LBP is person-specific and illustrates the heterogeneous nature of non-specific LBP. It may include:

- self-management
- exercise
- manual therapies
- psychological therapy (such as ACT or cognitive behavioural therapy (CBT), often associated with chronic pain)
- combined physical and psychological programmes
- return to work programmes.

Digital technology referrals can be either self- or clinician-led. Therefore, safety netting features such as risk stratification and red flag identifiers are important to ensure people who have specific conditions are identified as early as possible.

The current care pathway paradigm necessitates the health care practitioner (HCP) to coordinate and control a person's access to care. This, combined with waiting lists, act as a barrier to access care for non-specific LBP. The diverse nature of the digital technologies means their implementation may be suited to different stages of the care pathway, and in replacement of or addition to current care programs.

Digital technologies can be used as replacement to certain components of the care pathway or as an adjunct to current standard care. The type of care provided is likely to depend on multiple factors, such as comorbidities, pain severity, or if the LBP is acute or chronic. It is important to note that digital technologies for self-management of nonspecific LBP are not homogeneous, with different focuses based on the characteristics of the person with back pain. For example, technologies can be designed for either chronic LBP, acute LBP or a mixture of both.

Special considerations including issues related to equality

No further equality issues have been identified since the publishing of the Scope.

4 Clinical evidence selection

4.1 Evidence search strategy and study selection

Searches were conducted to identify studies of digital technologies for managing LBP. A single set of searches was conducted to identify both clinical and economic evidence. The searches were conducted in a range of resources including research published in the journal literature, conference abstracts and ongoing research. The searches were conducted in July 2023.

The EAG searches retrieved a total of 3,874 records after elimination of 2011 duplicates. Titles and abstracts were sifted by 1 reviewer (the first 10% assessed by 2 reviewers independently) based on the intervention and population; due to the volume of literature identified, studies in people with MSK pain were excluded unless the abstract listed non-specific LBP as subgroup. A total of 400 full text papers were

retrieved and examined by one reviewer (first 10% assessed by 2 reviewers) to select those meeting the scope definition of an eligible technology. Due to the volume of literature provided, at this point the EAG agreed with NICE that further study selection should limit to studies of the 8 interventions listed in the <u>final scope</u> with the addition of PhioEngage (EQL Ltd), a technology included by NICE following publication of the final scope. Company submissions were received from 4 of the 9 companies (submissions for ACT for PAIN, getUBetter, Hinge Health Digital MSK Clinic ('Hinge'), Pathway through Pain). 83 documents provided by company submissions were examined and 5 relevant studies not identified by the EAG searches were added to full text screening.

Full details of the search methods are provided in Appendix A – Search methods

4.2 Included and excluded studies

A total of 16 studies (reported in 31 papers or trial records) were identified in the clinical review. Of these studies, 12 were prioritised for further data extraction and are summarised in Table 4.1. For 1 of these studies (a getUBetter retrospective case series) the defined population was unclear, but clarification from getUBetter Ltd was sought and it was confirmed that only people with non-specific LBP were included. 4 studies were deprioritised and are summarised in Appendix E. These studies, including 1 Kaia app pilot RCT and 3 retrospective studies provided by getUBetter Ltd, were deprioritised due to uncertainty about whether people with non-specific LBP were included, and are summarised in Appendix E. Correspondence from 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.

A list of 369 studies excluded at full text is provided in Appendix B.

Table 4.1: Studies selected by the EAG as the evidence base

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|--|---|--|--|--|
| getUBetter | | • | · | |
| Wanless 2019 (Wanless and McClellan 2019) | Design : Retrospective case series, semi-quantitative survey GREEN | Participants : 10 people with LBP (not specified to be non-specific) and 10 clinicians/experts | Clinician experience Patient experience GREEN | People are not specified to have non-specific LBP. |
| Location: UK | Intervention: getUBetter GREEN Comparator: NA GREEN | Setting: Not reported (NR) GREEN Place in pathway: Unclear – app in 'pre-implementation' phase of embedding into MSK pathway. GREEN | | The population was not clearly defined, but clarification from getUBetter Ltd was sought and it was confirmed that only people with non-specific LBP were included. |
| Hinge | | | | |
| Shebib 2019 (Shebib et al. 2019) Location : USA Associated publications: (Hinge Health 2017) CT record | Design: RCT GREEN Intervention: Hinge in addition to usual care (All participants received the same version of the program, and there were no major app updates during the course of the trial – version number NR, patients recruited in 2017). Sensor-guided exercise therapy. GREEN Comparator: 3 digital education articles in addition to usual care (including physician visits, pain medication, diagnostic imaging, | Participants: 177 people with chronic non-specific LBP randomised. GREEN Setting: employees and their dependents invited to participate across 12 employer locations. GREEN Place in pathway: NR GREEN Acute versus (Vs) Chronic LBP: Chronic (pain for ≥ 6 weeks over last 12 months) | Modified Von Korff (MvK) Scales pain and disability Oswestry Disability Index (ODI) Pain intensity measured by visual analogue scale (VAS) Interest in surgery GREEN | Eligible applicants with greater pain, disability and surgery intent were prioritised for enrolment. EAG considers this may affect generalisability. |

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| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|--|--------------|
| | and potential recommendations for later injections and/or surgery). GREEN | Setting: NR, likely mixed (employees invited to participate) | | |
| Bailey 2020 (Bailey et al. 2020) Location: US | Design: Retrospective case series GREEN Intervention: Hinge (version NR, cutoff for recruitment 2019). Included sensor-guided exercise therapy. GREEN Comparator: NA GREEN | Participants: 10,264 adults with knee pain (n=3,796) or LBP (n=6,486) LBP subgroup: 6,468 adults with self-reported LBP for > 12 weeks and no red flag symptoms including signs of fracture, joint instability, infection, cancer and Claudia equina syndrome. Mean age 42.58 (SD: 10.91), female 4,981 (48.53%), Mean body mass index (BMI) 29.76 (SD: 7.11). GREEN Acute Vs Chronic LBP: Chronic Setting: NR (Participants were employees from office-based or service-based roles, and their dependents) GREEN Place in pathway: NR GREEN | VAS for pain MvK scale Patient Health Questionnaire-Nine (PH9-Q) for depression Generalised Anxiety Disorder Assessment (GAD-7) for anxiety WPAI scale Participant satisfaction GREEN | |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|---|---|
| Toelle, 2019 (Toelle et al. 2019) Location: Germany Associated publications: (Kaia Health Software GmbH 2018) CT record | Design: RCT GREEN Intervention: Kaia app (Kaia Health Software GmbH, Munich, Germany) (version not reported, patients recruited 2017 to 2018) GREEN Comparator: 6 physiotherapy sessions and online education GREEN | Participants: 101 people with non-specific LBP lasting 6 weeks to 1 year prior to inclusion. Kaia app: 53 people randomised, 48 included (42 completed follow-up): mean age 41 (SD 10.6), female 35 (72.9%), chronic LBP (≥3 months) 39 (81.3%) Physiotherapy: 48 people randomised, 46 included (44 completed follow-up): mean age 43 (SD 11.0), female 31 (67.4%), chronic LBP (≥3 months) 37 (80.4%) Acute Vs Chronic LBP: Mixed GREEN Setting: Mixed (referred (GP) and self-referred) GREEN Place in pathway: Interested people submitted by GP or via Facebook advertisements and website announcement. GREEN | Primary: Pain intensity (NRS 1- 10) Secondary: NRS 11 point pain scale Hannover Functional Ability Questionnaire (HFAQ) Graded Chronic Pain Scale (GCPS) Physical and mental wellbeing (VR-12) Adherence Adverse events GREEN | Participants and investigators not blinded due to nature of intervention. Comparator is standard care physiotherapy plus online resources sent via weekly emails with brief motivating message, which may constitute a more involved intervention than standard care. Authors report that "the recommended structured education of patients regarding back pain in current guidelines was more emphasized in the control group, than could be expected in standard care conditions" If so, the comparison may be less favourable to the Kaia app. Sample size met power analysis for primary outcome of pain level at 12-week follow-up – though authors note underpowered for |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|---|---|---|---|
| | | | | between-group comparison of small effect in pain reduction. |
| | | | | Per protocol analysis. |
| Priebe 2020 (Priebe et al. 2020a) Location: Germany Associated publication: (Projektzentrale Rise-uP 2018) CT record | Design: Cluster RCT GREEN Intervention: Rise-uP intervention, including 1) electronic case report form; (eCRF), 2) a treatment algorithm for guideline- based clinical decision making of GPs, 3) teleconsultation between GPs and pain specialists for patients at risk for development of chronic back pain; and 4) a multidisciplinary mobile back pain app for all patients (Kaia app). AMBER Comparator: Usual care provided by GPs (as per German national guidelines) GREEN | Participants: 1245 people with non- specific LBP, at 81 healthcare centres. Kaia app: 933 people with non-specific LBP, female 65%, age mean 42.0 (SD 12.4) Usual care: 312 non specific LBP patients, female 64%, age mean 37.0 (SD 12.6) GREEN Acute Vs Chronic LBP: Acute Pain status: Kaia app: GCPS grade 1: 28% GCPS grade 2: 21% GCPS grade 2: 21% GCPS grade 3: 47% GCPS grade 4: 4% Usual care: GCPS grade 1: 25% GCPS grade 2: 26% GCPS grade 3: 43% GCPS grade 3: 43% | Pain intensity (NRS 11 point scale) Hannover Functional Ability Questionnaire Veterans RAND 12 Item Health Survey Depression-Anxiety- Stress-Scale GREEN | Kaia app evaluated as 1 part of a 4 component intervention. |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|---|---|
| | | Setting: Mixed (Patients were recruited by participating GPs or from Facebook advertisements). GREEN Place in pathway: NR GREEN | | |
| Priebe 2020 (Priebe et al. 2020b) Location : Germany | Design: Retrospective cohort study (extracted as single-arm data) Intervention: Kaia app v1 (Kaia Health Software GmbH, Munich, Germany) GREEN Comparator: Kaia app v2 (version used individual user feedback collected in the course of app usage to tailor the individual training program, and included push notifications) AMBER | Participants: Patients with low back pain absent specific causes.Kaia app v1:180 users, female 105, mean age 33.94 (SD 10.86).Kaia app v2:153 users, female 67, mean age 46.96 (SD 13.1)Acute Vs Chronic LBP: NR GREENGREENSetting: Self-referred (User data were collected from individuals who downloaded the app and used it on their own initiative. Anonymised data extracted from company server).GREENPlace in pathway: NR, users | Pain intensity (NRS 11 point scale) GREEN | Compared different iterations of the same app. Absent an eligible comparator this was extracted as a single-arm case series. |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|---|---|
| | | downloaded app on own initiative GREEN | | |
| Clement 2018 (Clement et al. 2018) Location : Austria, Germany Switzerland, the UK and the US Associated publications: Huber 2017, (Huber et al. 2017) | Design: Retrospective cohort study (extracted as single-arm data) GREEN Intervention: Kaia app version 0.x (Kaia Health Software GmbH, Munich, Germany). The Kaia app involves daily back pain-specific education, physiotherapy, and mindfulness techniques. The content for an individual patient is updated daily depending on the patient's status of knowledge, practice, and progress. GREEN Comparator: Kaia app version 1.x (Kaia Health Software GmbH, Munich, Germany). The updated content features an increased pool of each of the different exercise types (physiotherapy, mindfulness, and education). Furthermore, exercises in each of the categories are customized more clearly to the user's feedback. AMBER | Participants: 1251 adults receiving medical treatment for LBP and no history of indicators for specific causes of back pain ("red flags"). App users who registered before March 2017 were eligible. Version 0.x: n=196, mean age 34.8 (SD: 11.0), 114/195 (58.2%) female, BL NRS pain mean 4.41 (SD: 11.6). Version 1.x: n=1,055, mean age 45.6 (SD:11.6), female 634/1055 (49.3%), BL NRS pain mean 4.19 (SD:1.57). GREEN Acute Vs Chronic LBP: NR Setting: NR, likely self-referred or mixed (People were recruited via online channels including Facebook, Google advertisements, company home page). Anonymised user data extracted from company server. | Adherence Dropout rate NRS GREEN | Compared different iterations of the same app. Absent an eligible comparator this was extracted as a single-arm case series. |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|--------------------------|---|
| | Users were divided into 2 groups to reflect whether they signed up to one of the first versions (version 0.x) or version 1.x (starting with 1.4) depending on whether they signed up before or after the release date of version 1.4 (users signing up before April 30, 2017 Vs May 1, 2017 or later). | GREEN Place in pathway: Outpatient LBP rehabilitation GREEN | | |
| Jain 2021 (Jain et al. 2021) Location: International | Design: Retrospective case series GREEN Intervention: Kaia app GREEN Comparator: NA GREEN | Participants: 138,337 adults receiving medical treatment for LBP with no history of indicators for specific causes (red flags) who were active on the Kaia app in 2018 or 2019. 76,906 (55.6%) female, 57,152 (41.3%) male, 4,279 (3.1%) unspecified. GREEN Acute Vs Chronic LBP: NR Setting: Self-referred (International users of the Kaia app. App use data). GREEN Place in pathway: NR GREEN | Adverse effects GREEN | Participants with no indicators for specific LBP causes. Non-specific not confirmed. Retrospective self- reporting of possible AEs after cessation of using intervention may result in underreporting of AEs. Users were not prompted to specify if there was a temporal relationship between AEs and app use. Due to privacy laws, users could opt-out of providing personal demographic and app use data which may have impacted analysis of |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|--|--|--|---|---|
| | | | | demographic and app use on AEs reporting. |
| selfBACK | | 1 | | |
| Sandal 2021 (NCT03798288) (Sandal et al. 2021) Location: Denmark and Norway Associated publications: (Sandal et al. 2019) Protocol (University of Southern Denmark 2019) CT record (Overas et al. 2022) Secondary analysis (Rasmussen et al. 2020) Implementation | Design: 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%), GREEN 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 | Mean difference in RMDQ scores Average and worst LBP intensity levels in the preceding week (VAS) Pain Self-Efficacy Questionnaire Fear-Avoidance Beliefs Questionnaire physical activity subscale EuroQol-5 Dimension questionnaire EuroQol visual analog scale Global Perceived Effect scale Adverse events GREEN | The planned sample size of at least 350 participants (175 in each group) was based on a power of 90% to detect a 2-point mean group difference in RMDQ score at 3 months. Sample size reached. ITT analysis conducted. |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|---|--|
| and analysis protocol (Rughani et al. 2023) Secondary analysis (Svendsen et al. 2022) Nested qualitative process evaluation | | Place in pathway : After clinical assessment and diagnosis and as addition to usual care GREEN | | |
| Sandal 2020 (Sandal et al. 2020) (NCT03697759) Location : Denmark and Norway Associated publications: (University of Southern Denmark 2018) CT record | Design: Single-arm trial GREEN Intervention: selfBACK GREEN Comparator: NA GREEN | Participants: 51 patients with non-specific LBP (specified in CT record) randomised. GREEN Acute Vs Chronic LBP: Mixed Setting: Referred (primary care including GP, physiotherapy, chiropractic serving; or outpatient hospital facility). GREEN Place in pathway: Patients seeking care from primary health-care practice. GREEN | RMDQ Pain intensity (NRS 11 point scale) PSEQ PASS Work ability index PSFS EuroQoL BIPQ GREEN | No methods used to account for missing data. |
| Nordstoga 2020 (Nordstoga et al. 2020) Location : Norway and UK | Design: Prospective cohort study (extracted as single-arm data) GREEN Intervention: Stage 1 – selfBACK app version with only physical activity component of the intervention and a web- | Participants: adults with ongoing or chronic non-specific LBP of any duration or severity. GREEN | User activity 10-item SUS Acceptability Dropouts GREEN | Comparator was an upgraded version of the app, not eligible comparator – extracted as single-arm data. |

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| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|----------------------------|--|--|----------|---|
| | questionnaire to collect information to tailor self-management plans. GREEN Comparator: Stage 2 – selfBACK app version that incorporated 3 self-management components (physical activity, exercises and education). GREEN | Stage 1: N=16 patients, mean age 51.1 (SD:13.9, range 23-71), mean BMI 26.2 (SD:4.2, range 18.8-32.8), 10 male. Recruited from a university physiotherapy, university staff and student population by email and the wider public by media release in Scotland between November 2017 and February 2018. Study duration 4 weeks. Stage 2: N=11 patients mean age 43.0 (SD:7.6, range 32-56), mean BMI 25.2 (SD:3.2, range 18.8-29.5), 5 male. Recruited from a hospital back and neck outpatient clinic and the wider public in Norway between April 2018 and May 2018. Acute Vs Chronic LBP: Chronic Setting: Mixed (Participants recruited from outpatient clinics, university staff and students and wider public through media advertisement). GREEN Place in pathway: Self-management of non-specific LBP. | | Small sample size in both stages. Mixed population in each stage comprised of participants with mild to moderate and ongoing or chronic LBP. |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|---|--|--|---|--|
| Geraghty 2018 (Geraghty et al. 2018) Location: UK Associated publications: (Geraghty et al. 2015) Protocol (Geraghty et al. 2020b) Post-trial questionnaire (University of Southampton 2013) CT record | Design: 3-arm RCT (feasibility) Intervention #1: SupportBack plus usual care. 6-week programme (1 session per week) GREEN Intervention #2: SupportBack plus physiotherapist telephone support plus usual care. Up to 1 hour total of physiotherapist telephone support (split into 3 calls) to provide support, encouragement, clarifications and reassurance. AMBER Comparator: Usual care (without restrictions, varying from no care beyond initial GP consultation to a range of treatment including physiotherapy or pain clinics). GREEN | Participants: 87 people with current LBP (within last 2 weeks) and without spinal pathology (infection, fracture or cancer) recruited February to September 2015. GREEN SupportBack + usual care: 30 people randomised, 25 analysed. Characteristics n=29: mean age 54.5 (SD: 13.7), female 19 (65.2%), mean LBP-related disability (RMDQ) 6.6 (SD: 4.6) SupportBack + physiotherapist support + usual care: 29 people randomised, 22 analysed. Characteristics n=27:, mean age 59.3 (SD: 10.4), female 17 (63.0%), mean LBP-related disability (RMDQ) 7.7 (SD:4.7) Usual care: 28 people randomised, 26 analysed. Characteristics n=27: mean age 60.3 (SD: 16.3) years, female 15 (55.6%), mean LBP-related disability (RMDQ) 6.8 (SD: 4.9). Acute Vs. Chronic LBP: NR Setting: Referred (Primary care GP) GREEN | Recruitment Adherence Withdrawals Physical activity (IPAQ- SF and additional questions) Pain duration and intensity Health service cost Patient satisfaction RMDQ Reduction in pain intensity Risk of persistent disability Fear of movement Catastrophising beliefs Patient enablement Patient expectation of positive outcome (CEQ) Health-related QoL (EQ-5D 3L). GREEN | Non-responders contacted by telephone by a blinded research assistant to collect key outcomes. Participants not blinded due to nature of the intervention. Intervention #2 received additional physiotherapist telephone calls to support the use of SupportBack. The type of usual care provided in the comparator group is not specified. Sample size underpowered to detect significant differences. Exploratory trial – "caution is required when interpreting the exploratory analysis of clinical outcomes as, due to the feasibility aims of this trial, it was not powered to determine effectiveness." |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|-------------------------|----------------------------|--|----------|--|
| | | Place in pathway: Mixed primary care GREEN | | ITT analysis not conducted, only those completing treatment. |

Key: AE – Adverse event, BIPQ – Brief illness perception questionnaire, BL – Baseline, BMI – Body-mass index, CEQ – Communication effectiveness questionnaire, CT – Clinical trial, EAG – External assessment group, ED – Emergency department, EQ-5D 3L – EuroQol 5 dimension, GAD-7 – Generalised anxiety disorder assessment, GCPS – Graded chronic pain scale, HFAQ – Hannover functional ability questionnaire, IPAQ-SF – International physical activity questionnaire – Short form, ITT – Intention-to-treat, LBP – Low back pain, MSK – Musculoskeletal, MvK – Modified Von Korff; NA – Not applicable, NR – Not reported, NRS – Numeric pain rating, ODI – Oswestry Disability Index 33, PASS – Patient acceptable symptom state, PH9-Q – Patient health questionnaire-9, PSEQ - Pain self-efficacy questionnaire, PSFS – Patient specific functional scale, QoL – Quality of life, RCT – Randomised controlled trial, RMDQ – Roland-Morris disability questionnaire, SD – Standard deviation, SUS – System usability scale, VAS – Visual analogue scale, Vs – Versus.

GREEN: Study characteristic aligns with the scope

AMBER: Study characteristic does not fully align with the scope

5 Clinical evidence review

5.1 Overview of methodologies of all included studies

Of the 16 included studies, 10 were comparative and included 6 RCTs comparing 4 LBP digital technologies to standard care (Geraghty et al. 2018, Jain et al. 2022, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019). The remaining 4 included 1 prospective and 3 retrospective cohort studies comparing app users to non-app users (Health Innovation Network Unpublished) or comparing different versions of 2 apps (Clement et al. 2018, Nordstoga et al. 2020, Priebe et al. 2020b), and so are considered as single-arm evidence due to the lack of an eligible comparator. The 6 non-comparative studies included 1 prospective single-arm trial (Sandal et al. 2020) and 5 retrospective case series (Bailey et al. 2020, Health Innovation Network 2022, Jain et al. 2021, NHS Foundation Trust 2022, Wanless and McClellan 2019).

5 studies (1 pilot RCT and 4 retrospective studies) did not clearly report whether people with specific or non-specific LBP were included (Health Innovation Network 2022, Health Innovation Network Unpublished, Jain et al. 2022, NHS Foundation Trust 2022, Wanless and McClellan 2019). This included 1 Kaia app pilot RCT and all getUBetter studies. Kaia Health and the pilot RCT authors were contacted to clarify the population, but no response was received. getUBetter Ltd were contacted to clarify the populations, and their response clarified that all studies included people with specific LBP except 1 retrospective case series (Wanless and McClellan 2019). This study was therefore prioritised. In total, 4 of the 16 studies were deprioritised and not extracted in full due to people with specific back pain being included, or this not being clearly reported.

5 RCTs (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019), 1 single-arm trial (Sandal et al. 2020), 1 prospective case series (Nordstoga et al. 2020) and 5 retrospective case series (Bailey et al. 2020, Clement et al. 2018, Jain et al. 2021, Priebe et al. 2020b, Wanless and McClellan 2019) were prioritised for further extraction. The remainder of this report summarises these 12 studies.

Patients and settings

The evidence-base evaluated the use of technologies in people referred by primary care providers or physiotherapists, people who self-referred, and mixed populations of referred and self-referred people. 2 studies did not specify whether people were referred or self-referred (Bailey et al. 2020, Shebib et al. 2019) but are likely to have included a mixture of people and so these are grouped with mixed referral settings. 1 study evaluated people with acute LBP (Priebe et al. 2020a), 3 studies evaluated people with chronic LBP (Shebib et al. 2019, Nordstoga et al. 2020, Bailey et al. 2020), and 3 evaluated populations with both acute and chronic LBP (Sandal et al. 2020) (Sandal et al. 2021, Toelle et al. 2019). 5 studies (Clement et al. 2018, Geraghty et al. 2018, Jain et al. 2021, Priebe et al. 2020b, Wanless and McClellan 2019), did not clearly report whether people had acute or chronic LBP, but are likely to have included both and so are grouped with mixed population studies throughout this report:

- Acute LBP: 1 cluster RCT in a mixed referral setting in Germany comparing against usual GP care (Priebe et al. 2020a).
- Chronic LBP: 3 studies in mixed referral or unclear referral settings including 1 parallel RCT in the US comparing an eligible technology to standard care plus educational articles (Shebib et al. 2019), 1 prospective case series in the UK and Norway (Nordstoga et al. 2020) and 1 retrospective case series in the US (Bailey et al. 2020).
- Mixed LBP:
 - 4 studies in referred people including 1 RCT comparing against usual GP care in Denmark and Norway (Sandal et al. 2021), 1 RCT comparing against usual GP care in the UK (Geraghty et al. 2018), (Geraghty et al. 2018, Sandal et al. 2021)1 single-arm trial in the US (Sandal et al. 2020) and 1 retrospective case series in the UK (Wanless and McClellan 2019).
 - 3 retrospective case series in mixed referra settings identified from company user databases or recruited from social media and other online channels, including 1 in Germany (Priebe et al. 2020b) and 2 in international settings (Clement et al. 2018, Jain et al. 2021, Priebe et al. 2020b).
 - 1 RCT in a mixed referral setting in Germany comparing against physiotherapy with online educational materials (Toelle et al. 2019).

The EAG considered the population to meet the scope in all 12 studies due to reported inclusion of people with non-specific LBP (Nordstoga et al. 2020, Priebe et al. 2020a, Priebe et al. 2020b, Sandal et al. 2021, Sandal et al. 2020, Shebib et al. 2019, Toelle et al. 2019), or of people with LBP without spinal pathology (Geraghty et al. 2018) or red flag signs and symptoms (Bailey et al. 2020, Clement et al. 2018, Jain et al. 2021). One retrospective case series did not clearly report this, but the company clarified that only people with non-specific LBP were included (Wanless and McClellan 2019).

Interventions

Included studies assessed 5 technologies identified in the <u>NICE Scope</u>, including getUBetter (getUBetter Ltd) Hinge (Hinge Health), Kaia app (Kaia Health), selfBACK (selfBACK Consortium) and SupportBack (University of Southampton). No studies evaluated the in-scope technologies Ascenti Reach (Ascenti), ACT for PAIN (Pain Medicine Specialist Ltd), Pathway through Pain (Wellmind Health), or PhioEngage (EQL Ltd), a technology included by NICE following publication of the final scope.

4 technologies (Hinge, Kaia app, selfBACK, SupportBack) were evaluated in 5 RCTs comparing against usual care (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019). SelfBACK, SupportBack and Hinge were allocated adjunct to usual care in 3 RCTs (Geraghty et al. 2018, Sandal et al. 2021, Shebib et al. 2019). 1 RCT allocated people to the Kaia app as part of a broader Rise-uP care protocol, which authors reported differs from German national guidelines for LBP in that the StarT Back questionnaire to assess the risk of chronic pain is administered at the start of treatment rather than after 4 weeks of failed treatment, and the GPs of patients at high risk received a teleconsultation with a pain specialist from the Rise-uP medical staff (Priebe et al. 2020a). Only 1 RCT allocated people in the intervention arm (Kaia app) to the digital technology alone (Toelle et al. 2019). SelfBACK was also evaluated in a prospective single-arm trial (Sandal et al. 2020).

Hinge, Kaia app and selfBACK were also evaluated in case series:

• Hinge: 1 retrospective case series (Bailey et al. 2020).

- Kaia app: 2 retrospective cohort studies extracted as single-arm studies (Clement et al. 2018, Priebe et al. 2020b) and 2 retrospective case series (Huber et al. 2017, Jain et al. 2021).
- SelfBACK: 1 prospective cohort study extracted as a single arm study (Nordstoga et al. 2020).

SupportBack was not evaluated in any additional studies. getUBetter was solely evaluated in 1 retrospective case series (Wanless and McClellan 2019).

2 studies evaluating the Kaia app and 1 study evaluating selfBACK evaluated different iterations of their respective apps in different cohorts of patients and reported the different features of each iteration (Clement et al. 2018, Nordstoga et al. 2020, Priebe et al. 2020b). The remaining studies did not report which version of their respective technologies were used, though descriptions of the technology features were provided. It is unclear which version of the Kaia and selfBACK apps are used in the NHS and at the time of writing.

Comparator

Of the 5 comparative studies, 4 compared digital technologies to standard care and did not report in detail what treatments comparator arm people received (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019). The other RCT compared the Kaia app to 6 face-to-face physiotherapy sessions alongside online education (Toelle et al. 2019).

5.2 Critical appraisal of studies

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

5 included studies reported comparative data from RCTs (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019), of which 2 are 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 was a small feasibility trial, noted by authors as underpowered to determine effectiveness (including 87 people across 3 arms) (Geraghty et al. 2018).
- 1 RCT achieved the sample size determined to be required by power analysis for the primary outcome of change in pain level at 12 weeks (101 people), but the authors noted that the study was underpowered to conduct a between-group comparison of a small-effect pain reduction (Toelle et al. 2019).

The remaining 3 trials were adequately powered and performed appropriate analyses.

Blinding to the identity of interventions was not feasible due to the nature of the interventions. The EAG considers these trials to pose a potential risk of producing exaggerated treatment effects due to the subjective nature of the patient-reported outcomes extracted for this early value assessment. However, this risk cannot be avoided due to the participatory nature of these interventions. Overall, the EAG considers the RCTs to provide adequate quality evidence for the comparative effects of LBP apps.

Non-comparative studies were of lower quality, being predominantly retrospective (4 of 6 studies) and subject to higher proportions of missing data. Further, two case series may have included overlapping populations (Clement et al. 2018, Priebe et al. 2020b). We contacted study authors to clarify whether there was overlap but received no response.

The EAG had the following concerns regarding the generalisability of the 12 prioritised studies:

- Only 4 studies included UK populations: 1 RCT (Geraghty et al. 2018), 1 prospective case series (Nordstoga et al. 2020) and 2 retrospective case series (Clement et al. 2018, Wanless and McClellan 2019). No UK evidence was available for Hinge or SupportBack. The variable nature of current care for LBP across different countries means the results may be poorly generalisable to the UK setting.
- 4 retrospective case series anonymised user information from company databases with limited information on the clinical care received (if any) in addition to the app (Clement et al. 2018, Huber et al. 2017, Jain et al. 2021, Priebe et al. 2020b).

 1 study included people with acute LBP only, 3 studies included people with chronic LBP only, 3 included a mixed population of people with acute and chronic LBP and 5 studies did not specify whether people had acute or chronic LBP. Only 1 study in a mixed population provided subgroup data. Where provided, the EAG observed that definitions of 'chronic' LBP varied from the accepted definition in the UK. For example, the Shebib et al 2019 RCT defined chronic LBP as pain of at least 6 weeks duration within the last 12 months. It is therefore unclear whether these populations are generalisable to people who would use LBP apps in the UK.

5.3 Results from the evidence base

All clinical outcome data are presented in Table 13.4 to Table 13.11. Although company submissions provided some statements relating to the scope outcomes, none provided adequate information on the context of the data to enable extraction and/or incorporation into the results.

Intermediate outcomes (Table 13.4, Table 13.5 and Table 13.6)

Functional outcomes

Measurement of physical function was performed using several different tools in 5 RCTs (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2020, Shebib et al. 2019, Toelle et al. 2019) and 1 prospective single-arm trial (Sandal et al. 2021) reported functional outcomes. Evidence is limited, as different measurements were used which precludes comparison, and non-UK study findings may not be generalisable to the UK NHS setting. Further, the UK study was a feasibility trial with small sample sizes and no testing of results for significance.

- Acute LBP: 1 German RCT including people from mixed referral settings (Priebe et al. 2020a) reported that Hannover Functional Ability Questionnaire (HFAQ) scores improved in the Kaia app group and remained stable in the usual care group at 12 weeks, though the significance of this difference was not tested, and authors reported significantly lower scores at baseline in the Kaia app group compared to the usual care group (Priebe et al. 2020a).
- Chronic LBP: 1 US RCT in a mixed referral setting (Shebib et al. 2019) reported that Hinge plus usual care resulted in a significantly greater improvement in mean Modified Von Korff (MvK) disability score at 12 weeks compared with usual care (mean difference –13 (95% CI –19.3, –6.7) p<0.001).
- Mixed LBP:
 - Three studies reported outcomes based on the Roland Morris Disability Questionnaire (RMDQ): 1 UK RCT conducted in primary care referral setting (Geraghty et al. 2018) reported a greater improvement in RMDQ scores in the SupportBack plus usual care and physiotherapist telephone support arm than the SupportBack plus usual care arm at 12 weeks (-1.3 (95% CI: -3.49 to 0.81 Vs -0.7, 95% CI: -2.77 to 1.35 respectively), though no statistical comparison was made and the change in the usual care arm was not reported. 1 RCT (Sandal et al. 2021) including people from a primary referral setting in Denmark and Norway reported that, at 3 months, people receiving selfBACK plus usual care had significantly lower mean RMDQ scores than people receiving usual care (mean -0.79, 95%CI -1.51 to -0.06, p=0.03), and that a significantly greater proportion of people in the selfBACK arm compared with usual care arm achieved at least a 4 point improvement in RMDQ at 3 months (adjusted OR 1.76, 95% CI 1.15 to 2.70, p=0.01). 1 prospective single-arm trial (Sandal et al.

2020) including people from a primary referral setting in Denmark and Norway reported that selfBACK users experienced an improvement in mean RMDQ score, though significance was not tested.

- HFAQ: 1 RCT including people from mixed referral settings in Germany reported no significant difference between the Kaia app arm and physiotherapy plus online education arm in HFAQ scores at 6 and 12 weeks (Toelle et al. 2019).
- Other outcomes: 1 UK RCT conducted in primary care referral setting (Geraghty et al. 2018) reported greater improvement in International Physical Activity Questionnaire and on a modified enablement scale in the SupportBack plus usual care and physiotherapist telephone support arm than the SupportBack plus usual care arm at 12 weeks, although significance was not tested. Mean change scores were not reported for the usual alone care arm. 1 prospective single-arm trial (Sandal et al. 2020) including patients from a primary referral setting in Denmark and Norway reported that selfBACK users experienced an improvement in mean Patient Specific Functioning Scale score at 6 weeks, though significance was not tested.

None of the data reported in the studies for functional outcomes were considered suitable for use in the EAG economic model. This was because the functional outcomes described above could not be linked to either HRQoL or resource use. Any functional outcome that can be mapped to EQ-5D-3L or be related to resource use could be useful to any economic analysis. Section 10.3 describes how future analysis could incorporate pain score data, providing it can be stratified by severity.

Treatment Satisfaction

3 studies, including 1 RCT (Sandal et al. 2021) and 1 prospective single-arm trial (Sandal et al. 2020) conducted in Denmark and Norway, and 1 prospective case series conducted in the UK and Norway (Nordstoga et al. 2020), reported different quantitative patient satisfaction measures for use of the selfBACK app.

• Chronic LBP: 1 prospective case series in a mixed referral setting reported patient satisfaction questionnaire results. 11 of 16 (69%) People from the UK who used an early selfBACK app version responded that they would download the app again, and 9 of 10 (90%) of Norwegian people using an updated app

version responded that they would like to use selfBACK frequently (Nordstoga et al. 2020).

Mixed LBP: 1 selfBACK RCT (Sandal et al. 2021) in a primary referral setting in Denmark and Norway reported a significant difference in favour of selfBACK on the Global Perceived Effect Scale (GPES) score at 3 months (0.70, 95% CI 0.39 to 1.01, p<0.001). A difference in favour of selfBACK was also reported at 9 months, though the significance was not tested statistically. 1 prospective single-arm selfBACK trial (Sandal et al. 2020) in a primary referral care setting. This study reported GPES by the proportion of people at each rating, and reported that at 6 weeks the per protocol population 2/43 (5%) rated their condition after the intervention as "very much worse," 3/43 (7%) rated it "slightly worse," 13/43 (30%) rated it "no change," 14/43 (33%) rated it "slightly better," 8/43 (19%) rated it "somewhat better" and 1/43 (2%) rated it "very much better" used a patient acceptable symptom state measure and reported that among 43 people who completed the trial, 20 (47%) reported having reached an acceptable symptom state at 6 weeks (Sandal et al. 2020).

One retrospective case series conducted in a primary care referral setting in the UK (whether people with acute or chronic LBP was not reported) reported the Patient Education Materials Assessment Tool for Audiovisual Materials (PEMAT-A/V) score as measured by 10 patients and 10 clinicians, in which getUBetter scored 60% for understandability and 75% for actionability (Wanless and McClellan 2019). Higher scores indicate greater understandability and actionability, but in the absence of PEMAT-A/V scores for other technologies for comparison it is difficult to draw conclusions from this data. This study also reported that the majority (the number was not reported) of the 10 people with non-specific LBP found the app helpful, with 1 reporting that they didn't want to use the app.

None of the data reported in the studies for treatment satisfaction were considered suitable for use in the EAG economic model. This was because the treatment satisfaction outcomes could not be linked to either HRQoL or resource use.

Pain Self-Efficacy

3 studies in mixed acute and chronic LBP, referred in a primary care setting, reported data for pain self-efficacy measures for 2 technologies.

1 3-arm RCT conducted in the UK (Geraghty et al. 2018) reported that Pain Catastrophising Scale scores improved from baseline to 12 weeks in the SupportBack plus usual care alone arm (mean difference -1.5, 95% CI: -6.37 to 3.40) and worsened (a higher score indicates worse pain catastrophising) in the SupportBack plus usual care and physiotherapy teleconsultation arm (mean 4.2, 95% CI: -0.58 to 8.90). The mean change in the usual care arm was not reported.

We note that this was a feasibility RCT with small sample sizes (a total of 57 per protocol people across treatment arms analysed for this outcome) and no tests of statistical significance were reported (Geraghty et al. 2018).

1 RCT conducted in Denmark and Norway (Sandal et al. 2021) found that selfBACK plus usual care resulted in a statistically significantly better (higher scores indicating greater self-efficacy in managing pain) Pain Self-Efficacy Questionnaire (PSEQ) score at 3 months compared with usual care (2.52 95% CI, 1.04-3.99, p = .001) in the ITT population (232 selfBACK arm, 229 usual care arm). The prospective single-arm trial evaluating selfBACK also measured PSEQ and reported a change score from baseline to 6 weeks of 2.0 (95% CI: 0.4 to 3.6). We note that this was a small pilot trial with a per protocol population of 43 people and differences were not tested for significance (Sandal et al. 2020).

None of the data reported in the studies for pain-self efficacy were considered suitable for use in the EAG economic model. This was because the reported pain scores could not be linked to either HRQoL or resource use. These two aspects would be fundamental to any economic analysis. Section 10.3 describes how future analysis could incorporate pain score data, providing it can be stratified by severity.

Work productivity

2 case series studies of people with chronic LBP from a primary referral setting (Sandal et al. 2020) or from a mixed referral setting (Bailey et al. 2020) reported data for this outcome based on different measures of work productivity. Neither study was conducted in the UK. Both studies reported improvements in work ability or productivity.

The prospective single-arm selfBACK trial reported an improvement in Work Ability Index score of mean -0.2 (95% CI: -0.8 to 0.5) from baseline to 6 weeks in a per protocol population of 43 people. The retrospective Hinge case series reported an improvement in Work Productivity and Activity Impairment Questionnaire from mean 34.12 (SD: 26.37) at baseline to mean 12.24 (SD: 15.58) at 12 weeks in 6,486 people (Bailey et al. 2020). Differences were not tested for significance.

None of the data reported in the studies for work productivity were considered suitable for use in the EAG economic model. This was because the productivity differences could not be adequately linked to lost earnings or output to the economy.

Intervention adherence

5 studies including 2 RCTs (Geraghty et al. 2018, Sandal et al. 2021) and 3 retrospective case series (Bailey et al. 2020, Clement et al. 2018, Priebe et al. 2020b) reported data for adherence.

- Chronic LBP: 1 UK RCT including people in a primary care referral setting (Geraghty et al. 2018) reported that 32% of people in the SupportBack plus usual care arm and 41% of people in the SupportBack plus usual care and telephone physiotherapist support arm completed all 6 app sessions over the 12week study period (Geraghty et al. 2018). 1 US retrospective case series including people from a mixed referral setting reported that 4,676 of 6,486 (72.29%) people completed at least one exercise session or educational paper in weeks 9-12 (Bailey et al. 2020).
- Mixed LBP: 3 studies reported adherence in 3 different measures, including 1 RCT including people from a primary care referral setting (Sandal et al. 2021) and 2 retrospective case series including people from a mixed referral setting in Germany (Priebe et al. 2020b) and Germany, Austria Switzerland, the UK, and the US (Clement et al. 2018). The selfBACK RCT reported that 181 of 232 (78%) of participants allocated adhered to the app, defined as creating ≥6 selfmanagement plans during the first 12 weeks after randomisation (Sandal et al. 2021). A retrospective case series reported that of 196 users of an early Kaia app version, 54.1% were active at week 12 and 40.3% were active at week 24, while among 1,055 users of an updated Kaia app version 54.4% were active at week 12 and 36.1% were active at week 24 (Clement et al. 2018). 1 further retrospective case series of selfBACK found that 38% of 159 people using an

updated version, completed all 12 weeks of the Kaia app program (Priebe et al. 2020b).

The EAG economic model utilised the adherence data from Bailey et al. (2020), as it was the study that contained the largest cohort that was a mix of people who had been both referred and self-referred.

Engagement measures

7 studies including 3 RCTs (Priebe et al. 2020a, Shebib et al. 2019, Toelle et al. 2019),
1 prospective single arm trial (Sandal et al. 2020), 1 prospective case series
(Nordstoga et al. 2020) and 2 retrospective case series (Bailey et al. 2020, Jain et al. 2021) reported app engagement measures:

- Acute LBP: 1 RCT conducted in a German mixed referral setting reported that among the per protocol population. The Kaia app was used on an average of 25 days in across the 12-week study period. Authors reported that a correlation analysis between the level of pain improvement and the frequency of app usage revealed no significant correlation (r=0.019, p>0.05) (Priebe et al. 2020a).
- Chronic LBP: 1 RCT conducted in the US (Shebib et al. 2019), 1 prospective case series conducted in the UK and Norway (Nordstoga et al. 2020) and 1 retrospective case series conducted in the US (Bailey et al. 2020) reported engagement with different measures. All were conducted in mixed referral populations. The RCT reported that the average weekly engagement, defined as any progress towards the weekly goals, was 75% across 12 weeks among the 91 participants who started the Hinge program (Shebib et al. 2019). The prospective case series reported that 16 UK participants using an early selfBACK version with only a physical exercise component opened the app a mean number of 6.2 (range 0-95) times per day over a 4-week study period (Nordstoga et al. 2020). The retrospective Hinge case series reported that, after 12 weeks, the 6,486 LBP participants had engaged with the app a mean number of 8.36 weeks (Bailey et al. 2020).
- Mixed LBP: 1 RCT conducted in a German mixed referral setting (Toelle 2019) reported that the Kaia app was used on average on M = 35 days (SD = 22 days) among the per protocol population (42 people), with no methods to account for missing data from 11 people lost to follow-up. 1 prospective single-arm trial in a primary referral setting in Denmark and Norway (Sandal et al. 2020) reported that among all 51 included people across the 6-week study period the mean total number of visits to the selfBACK app was 65 (range 1 to 188) and the mean

number of days visiting the app was 22 (range 1 to 47). 1 retrospective case series in an international mixed referral setting (Jain et al. 2021) reported that among 138,337 Kaia app users from January 2018 to December 2019 the average number of active days per app user was 7.26 (Jain et al. 2021).

None of the data reported in the studies for engagement measures were considered suitable for use in the EAG economic model. This was because using intervention adherence was more suitable for use in the economic model, due to the simplified nature of the early analysis.

Clinician Satisfaction

1 retrospective case series conducted in a primary care referral setting in the UK (whether people with acute or chronic LBP was not reported) reported that on a staff experience questionnaire most (the number was not reported) staff reported that getUBetter enhanced the treatment pathway but was challenging to explain to patients due to both patient and clinician beliefs about best care being delivered by face-to-face consultation (Wanless and McClellan 2019).

None of the data reported in the studies for clinician satisfaction were considered suitable for use in the EAG economic model. This was because the reported clinician satisfaction outcomes could not be linked to either HRQoL or resource use.

Clinical outcomes (Table 13.7, Table 13.8, Table 13.9)

Surgical referrals

The impact of the technologies on surgical referral rates were not reported by any of the included studies.

2 studies, 1 RCT (Shebib et al. 2019) and 1 retrospective case series (Bailey et al. 2020), both in people with chronic LBP in mixed referral settings in the US, reported patient interest in or perceived likelihood of surgery. We note that this may not be generalisable to a UK NHS setting.

The RCT reported a significantly greater reduction in the proportion of people interested in surgery (based on a 0-1 visual analogue scale [VAS]) in the Hinge plus usual care arm compared with the usual care arm (mean difference -0.4, 95% CI -0.7, -0.1, p=0.01) (Shebib et al. 2019). 1 retrospective case series evaluating Hinge reported patient perception of surgery likelihood within 1 year on a 1-100 scale, which fell from mean 9.07 (SD: 17.98) at baseline to 2.88 (SD: 9.26) at 12 weeks (Bailey et al. 2020). The difference was not tested for statistical significance.

Patient reported outcomes (Table 13.10 and Table 13.11)

Patient reported outcomes were the most widely reported type of outcome across all studies.

Health-related quality of life

4 studies including 3 RCTs (Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019) and 1 prospective single arm trial (Sandal et al. 2020) reported health-related quality of life (HRQoL) outcomes. Evidence was not available from any UK studies. Use of digital technologies alongside usual care was associated with reduced impact on daily activities in 1 RCT of people with chronic LBP but there was no evidence of a statistically significant difference in HRQoL in comparative studies in populations with mixed acute and chronic LBP.

- Chronic LBP: 1 RCT, including people from a primary care referral setting in the US, reported that the use of Hinge plus usual care resulted in a significantly greater reduction in a 1-100 VAS impact on daily life score compared to usual care (Hinge plus usual care 113 people Vs usual care 64 people, mean difference: -11.8 (95% CI: -19.3, -4.3, p=0.002) at 12 weeks in the ITT population (Shebib et al. 2019).
- Mixed LBP: Comparative evidence indicated no significant effect of digital technologies on HRQoL outcomes compared to usual care. 2 RCTs, and 1 prospective single arm trial conducted in a primary care referral setting (Sandal et al. 2020) reported HRQoL with 3 different tools. 2 RCTs (selfBACK RCT conducted in a primary care referral setting in Denmark and Norway (Sandal et al. 2021) and the Kaia app RCT conducted in a mixed referral setting in Germany (Toelle et al. 2019), reported no significant difference in HRQoL scores between technologies plus usual care compared to usual care at 12 weeks based on the Veterans RAND 12-Item Health Survey mental and physical scores (Toelle et al. 2019) or EQ-VAS and EQ-5D scores (Sandal et al. 2021). The single-arm prospective trial conducted in Denmark and Norway reported an improvement on the EuroQol 100mm VAS scale of mean 9.2 (95% CI: 4.4 to 13.9) from baseline to 6 weeks in the per protocol population of 43 people, though the difference was not tested for significance (Sandal et al. 2020).

EQ-5D-3L and EQ-VAS scores from (Sandal et al. 2021) for HRQoL were used in the EAG economic model.

<u>Pain</u>

9 studies including 5 RCTs (Geraghty et al. 2018, Priebe et al. 2020a, Sandal et al. 2021, Shebib et al. 2019, Toelle et al. 2019), 1 prospective single-arm trial (Sandal et al. 2020) and 3 retrospective case series (Bailey et al. 2020, Clement et al. 2018, Priebe et al. 2020b) reported pain outcomes. Pain was assessed using several different tools, but 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 of chronic).

 Acute LBP: 1 RCT conducted in Germany in a mixed referral setting reported that the Kaia app resulted in a significantly greater percentage reduction in Numerical Rating Scale (NRS) pain index (mean of current, maximum, and average pain intensity over the last 4 weeks) than usual care (-33.3% Vs -14.3% p<0.001) and lower total pain scores (3.37 [SD 2.35] Vs 4.02 [SD 2.19], p<0.001) at 12 weeks in the per protocol population (Priebe et al. 2020a).

- Chronic LBP:
 - MvK scale: 1 RCT conducted in a mixed referral setting in the US found that Hinge plus usual care resulted in a significantly greater reduction in pain score compared with usual care plus 3 digital education articles using the MvK pain scale (mean difference Hinge plus usual care Vs usual care: -16.4, 95% CI -22, -10.9, p<0.001) in the ITT population (Shebib et al. 2019). 1 retrospective case series conducted in mixed referral settings in the US also used the MvK pain scale, and reported that in 4,676 of 6,468 Hinge program completers (of 6,468 overall people), there was a significant improvement of 51.4% (8.20 points, p<0.001) from baseline at 12 weeks (Bailey et al. 2020).
 - ∨AS scale: 1 RCT conducted in mixed referral settings in the US demonstrated a significant reduction in pain score from using Hinge plus usual care compared to usual care plus 3 digital education articles using the VAS pain score (mean difference Hinge plus usual care Vs usual care: -16 (95% CI: -22.5, -9.4) p<0.001) in the ITT population (Shebib et al. 2019). Significantly greater proportions of people achieved a minimum 30% reduction or 15 point reduction (Hinge plus usual care: 56/69 (81%) Vs usual care: 11/36 (31%) p<0.001) at 12 weeks (Shebib et al. 2019).
 - Graded chronic pain scales: The German Kaia app RCT, conducted in people from mixed referral settings, found no significant differences at 6 weeks and 12 weeks between the Kaia app and physiotherapy arms in graded chronic pain scales among a per protocol population chronic pain subgroup (Toelle et al. 2019).
- Mixed LBP:
 - NRS scores: 1 RCT conducted in Denmark and Norway evaluated people referred from primary care and reported that, at 3 months, selfBACK resulted in significantly lower average NRS pain intensity scores and worst pain intensity scores in the preceding week compared to usual care (mean difference -0.62 (95% CI, -0.99 to -0.26) p= 0.001 and mean difference -0.73, 95% CI -1.15 to -0.31, p=0.001 respectively) (Sandal et al. 2021). The prospective single arm trial of also reported that people using selfBACK experienced a reduction in average and worst NRS pain score (Sandal et al. 2020).
 - 1 UK RCT in a mixed population with acute and chronic LBP from a primary care referral setting reported that SupportBack plus usual care

with physiotherapist telephone consultations resulted in greater improvement in NRS baseline and larger reductions in the NRS average pain, NRS least pain score in the last 2 weeks and NRS pain index (mean of current, maximum, and average pain intensity over the last 4 weeks) than SupportBack plus usual care alone, though sample sizes were small and no statistical comparisons were made (Geraghty et al. 2018).

- 1 RCT conducted in Germany in people from mixed referral settings reported that the Kaia app resulted in significantly lower pain intensity on an NRS pain index compared to physiotherapy plus online education at 12 weeks, though noted that between-group difference in pain reduction was not significant (Kaia app: mean change = -2.4; physiotherapy and online education group: mean change = -2.0; p > 0.05) (Toelle et al. 2019).
- 2 retrospective case series studies evaluated the Kaia app in mixed referral settings reported NRS scores taken at baseline and the day of follow-up (Clement et al. 2018, Priebe et al. 2020b). 1 reported a significant improvement in NRS score in Kaia app users from baseline to 12 weeks both in people using version 1 (mean –0.50 (SD 2.04) p=0.003) and those using version 2 (mean –0.50 (SD 2.04) p=0.003) (Priebe et al. 2020b). The other reported a non-significant improvement in mean NRS score both in people using an early and an updated the Kaia app version from baseline to week 24, though the differences were not tested statistically (Clement et al. 2018).

None of the data reported in the studies for pain were suitable for use in the EAG economic model. This was because the reported pain scores could not be linked to either HRQoL or resource use. These two aspects are fundamental to any economic analysis. Section 10.3 describes how future analysis could incorporate pain score data, providing it can be stratified by severity.

Oswestry Disability Index Score

1 RCT conducted in people with chronic LBP in a mixed referral population in the US reported that Hinge plus usual care resulted in a significantly greater reduction in Oswestry Disability Scores (reduced scores indicate reduced impact of LBP on everyday life) compared to usual care at 12 weeks (mean difference-4.1 (95% CI: -6.5, -1.8, p<0.001) in the ITT population (Hinge 113 people, usual care 64 people) (Shebib et al. 2019). This RCT also reported significant differences in favour of Hinge plus usual

care in the proportion of per protocol people experiencing a 10 point or 30% reduction in ODI, reporting that 40 of 69 (58%) people in the Hinge arm reached this threshold compared to 9 of 36 (25%) people in the usual care arm (p=0.003) (Shebib et al. 2019). This finding may not be generalisable to a UK NHS setting.

None of the data reported in the studies for Oswestry Disability Score were considered suitable for use in the EAG economic model. This was because the reported Oswestry Disability Scores could not be mapped to EQ-5D-3L or related to any resource use.

Patient Experience

1 prospective case series evaluated people with chronic LBP reported the 10-item System Usability Scale after 4 weeks, reporting that 16 people from the UK using an earlier version of the selfBACK scored it a mean 64.7 points (SD: 21.2, range 10-95), while 10 (of 11 total) people from Norway, using a more recent version, scored it a mean 70.5 points (SD: 20.5, range: 45-95) (Nordstoga et al. 2020). Further, 10 people from Norway using the more recent version responded to a telephone interview, of whom 60% were neutral on whether the app helped with LBP management, 20 % found it useful and 20% found it not useful (Nordstoga et al. 2020).

None of the data reported in the studies for patient experience were suitable for use in the EAG economic model. This was because the reported patient experiences could not be linked to either HRQoL or resource use.

6 Adverse events and clinical risk

Adverse events

Adverse events (AEs) or patient safety data were reported in 4 studies for 3 digital technologies (Kaia app, selfBACK and SupportBack). Rates of AE reported were generally very low and indicate that the digital technologies evaluated in this early value assessment are plausibly safe.

<u>Kaia app</u>

2 studies reported AEs related to the Kaia app: 1 international retrospective case series evaluating 138,337 people receiving medical treatment for LBP with no history or indicators for specific causes of LBP who were active on the Kaia app (Jain et al. 2021) and 1 German RCT comparing 53 people with chronic non-specific LBP using the Kaia app to 48 people receiving physiotherapy and online education (Toelle et al. 2019).

A total of 142 AEs were reported by 125 out of 138,337 (0.09%) users of the Kaia app (average number of active days per app user was 7.26 between January 2018 and December 2019 (rate of AEs: 0.000014 per day). Of the 142 AEs reported 83 (58.4%) were reported to be increased pain, 25 (17.5%) unpleasant sensations, 19 (13.4%) headache, 7 (4.9%) dizziness, 4 (2.8%) sleep disturbances and 1 (0.7%) required surgery. AEs were most frequently reported by users who had between 0-99 active days on the app and were less frequently reported by users who had more active days on the app. There was a significantly increased risk of AEs amongst users between 25 and 34 years (OR 0.31, p=0.03), users between 55 to 64 years (OR 2.53, p=0.002), and users aged over 75 years (OR 4.36, p=0.02) (Jain et al. 2021) had a significantly increased risk of AEs. App users under 25 years (OR 0.21, p=0.15), between 35 and 44 years (OR 1.20, p=0.63) and between 65 to 75 years (OR 1.97, p=0.13) did not have a significantly increased risk of AEs.

Lumbar disc herniation was discovered in 1 patient using the Kaia app on a routine MRI during the study. However, this was considered to be unrelated to the intervention. No

adverse events were reported amongst the people receiving physiotherapy sessions and online education (Toelle et al. 2019).

<u>selfBACK</u>

One RCT conducted in Denmark and Norway compared 232 people with non-specific LBP using selfBACK in addition to usual care with 229 people receiving usual care alone (which consisted of advice or treatment offered by a clinician) at 3-month follow-up (Sandal et al. 2021). Whilst there were no AEs reported by users of the selfBACK App at 3-month follow-up, experiencing conflicting advice from the app and a healthcare professional was reported to be a barrier to sustained engagement (Sandal et al. 2021).

SupportBack

In a 3-arm feasibility RCT conducted in the UK amongst people with acute and chronic LBP without spinal pathology (infection, fracture or cancer), 30 people received SupportBack and usual care, 29 people received SupportBack, physiotherapist support and usual care, and 28 people received usual care alone (Geraghty et al. 2018).

2 hospital admissions were reported amongst in each of the 3 treatment arms being evaluated. The reason for hospital admissions was not reported; however, it was considered by the authors of the study to be very unlikely that the SupportBack intervention was a factor in the hospital admissions (Geraghty et al. 2018).

Withdrawals/discontinuations

Data on withdrawals and discontinuations was poorly and inconsistently reported across the identified studies. It was often not clear whether reported discontinuations were true discontinuations from the study, discontinuation (or non-engagement) with the digital technology or loss to follow up and, subsequently, how applicable this data would be in clinical practice.

7 Evidence synthesis

Findings across studies are discussed narratively. It was not feasible to undertake meta-analysis within the constraints of this early value assessment.

The evidence-base evaluated the use of technologies in patients referred by primary care providers or physiotherapists and mixed populations of referred and self-referred patients or where referral was unclear. The populations assessed also differed in with regards to the nature of the LBP; 1 study evaluated patients with acute LBP, 3 studies evaluated patients with chronic LBP, and 7 evaluated both acute and chronic patients or did not report this information.

There was insufficient evidence to inform a meta-analysis for any of the scoped technologies. 5 RCTs were identified that compared 4 different digital technologies to usual care (Hinge, Kaia app, selfBACK, SupportBack). Of the 5 RCTs, 2 were powered to test differences in effect size between treatment groups in their reported outcome measures (Priebe et al. 2020a, Shebib et al. 2019). 2 RCTs assessed the use of the Kaia app but in 1 study it was administered alongside usual care (Priebe et al. 2020a) while in the other RCT, patients were allocated to the digital technology alone (Toelle et al. 2019).

Furthermore, outcomes were reported inconsistently and across a wide range of measures making it difficult to draw any meaningful conclusions across the data.

8 Economic evidence

8.1 Economic evidence

A single set of searches was conducted to identify both clinical and economic evidence for the scoped technologies (see 4.1). Search methods are reported in Appendix A and study selection criteria is summarised in Appendix D. A total of 2 cost-effectiveness studies and 7 costing studies were identified and summarised below and in Table 8.1. The costing studies did not contain a full cost-effectiveness analysis but provide relevant economic evidence such as health care costs and resource use.

The 2 cost-effectiveness studies focused on chronic, non-specific LBP rather than acute back pain. Both cost-effectiveness analyses were conducted within Germany, and so the generalisability of evidence within a UK health-care setting should be considered.

Lewkowicz et al. (2022) conducted a cost-effectiveness analysis that compared digital therapeutic care (DTC) with treatment as usual (TAU) in Germany. The analysis simulated a cohort of patients using a Markov state-transition model. It used data from the Kaia app study, an RCT of a digital self-management app for chronic LBP, to inform efficacy data, cost data and transition probabilities. The self-management app focused on physical rehabilitation/self-management rather than psychological therapy such as CBT or ACT. Costs and QALYs associated with the different health states for both the intervention and comparator arm were totalled and the incremental difference calculated. The simulation found DTC was cost-effective compared with TAU, with an incremental cost-effectiveness ratio (ICER) of €5,486 per QALY.

Lewkowicz et al. (2023) was an adapted analysis of (Lewkowicz et al. 2022) and provided a probabilistic base case rather than a deterministic base case. Probabilistic sensitivity analysis was performed using a Monte Carlo simulation on the original base case model. This tested both parameter uncertainty and stochastic uncertainty. After undergoing the Monte Carlo simulation (10,000 iterations) the ICER was €34,315 per QALY. This differed from the original base case ICER of €5,486 per QALY. The large difference in the reported ICERs across both studies was due to the very small incremental effect on QALYs, estimated at less than 0.01 per QALY. In the Monte Carlo Simulation, the results were negatively skewed, and given that the incremental effect was already small (and statistically insignificant), this small movement in the effect had a large impact on the reported ICER.

7 costing studies were also identified and are summarised in Table 8.1. All 7 studies indicated that there is a potential for cost-savings to the healthcare system, although

not all were specific to the UK. The studies also reported data on the impact of resource utilisation and were examined for usefulness to the conceptual model. One of these costing studies reported data that was used in the economic model (getUBetter) (Health Innovation Network Unpublished). 3 of the studies were provided by Hinge Health (Optum 2022, Hinge Health 2022, Validation Institute 2023). All 3 had large population sizes (n=467, 8,414 and 748) and were conducted in the US. The resource-use described in these papers is therefore considered to be not generalisable to the UK. Not all costing studies were solely conducted in populations with non-specific LBP. However, given the limited evidence on healthcare resource use, a pragmatic approach was taken to include them as part of the economic evidence summary.

Table 8.1: Identified costing studies

| Study ID | Title | Study type | Narrative summary |
|----------------------------|--|---|---|
| Economic evaluat | ions | | |
| Lewkowicz et al. (2022) | Digital Therapeutic Care Apps With Decision-Support Interventions for People With Low Back Pain in Germany: Cost- Effectiveness Analysis | Cost – effectiveness analysis using a state-transition Markov model | An economic evaluation on the cost-effectiveness of a digital therapeutic care (DTC) app compared with Treatment as usual (TAU) practices in Germany. These TAU practices included face-to-face (F2F) physiotherapy and concomitant pharmacological treatment. Effectiveness data to inform the Markov model were derived and extrapolated from a previous digital self-management app RCT; the Kaia app RCT. The study used a health state-transition Markov model with 7 health states. This included a low-impact state, a high-impact state, a remission state, a healthy state and 3 treatment states representing treatment weeks 1 to 12. The model simulated the movement of individuals between states based on transition probabilities. Each of the states was associated with a different cost and utility value. This was used to compare the TAU with the intervention. Economic outcome data for the state-transition Markov model included: ICER of €5486 per QALY Incremental cost of €121.59 Additional 0.0221 QALYs The study has the same limitations as listed for Lewkowicz et al. (2023), given it is a |
| Lewkowicz et al. (2023) | Economic Evaluation of Digital Therapeutic | Cost – effectiveness analysis using a | deterministic version of the same model. An economic evaluation was carried out utilising a PSA using a Monte Carlo simulation. The paper built upon a previous cost-utility model of a DTC program for patients with nonacute LBP in Germany. The previous model had deployed a discrete health state-transition |

| Study ID | Title | Study type | Narrative summary |
|---------------------------|--|--------------------------------|---|
| | Care Apps for Unsupervised Treatment of Low Back Pain: Monte | ised Markov model t of Low | Markov chain with 7 health states, the same as Lewkowicz et al. (2022). This paper tested parameter and stochastic uncertainty with 10,000 iterations. In each iteration, the parameters were drawn from a pre-determined distribution. |
| | Carlo Simulation | | The model time horizon was 3 years and a cycle length of 4 weeks. The model used outcome data from the Kaia app study (such as follow-up rates). |
| | | | Economic outcome data for the Monte Carlo simulation included: Incremental cost of €135.97 |
| | | | |
| | | | Incremental 0.004 QALYs per year compared to in-person physiotherapy in Germany |
| | | | Incremental cost-utility ratio (ICUR) of €34,315.19 per additional QALY |
| | | | The study highlighted how the probabilistic analysis suggested the device was less likely to be cost-effective than the deterministic analysis, with a large difference in the estimated ICER. |
| | | | The study had some limitations, such as most of the resource use being determined by assumptions, which may be subject to unknown confidence intervals. It was not clear how these assumptions impacted the results of the analysis. The validity of impact on quality of life was also uncertain, given that the source used stated there was no impact on quality of life, and an earlier cut of the data is used with assumptions to extrapolate this for the model. |
| Costing studies | | | |
| Geraghty et al. (2018) | Using an internet intervention to support self- management of low back pain in | A pragmatic feasibility RCT | A pragmatic feasibility study was conducted that elicited the feasibility of a RCT for an internet intervention for LBP. The study also listed health economic outcomes, such as primary care costs, secondary care costs and back pain costs between the interventions and the comparator. The study used 3 arms: |
| | primary care: | | Usual care |
| | findings from a | | Usual care plus an internet intervention |
| | randomised | | osual vare plus an internet intervention |

| Study ID | Title | Study type | Narrative summary |
|----------|---------------------------------|------------|---|
| | controlled feasibility trial | | Usual care plus an internet intervention with additional physiotherapist telephone support |
| | (SupportBack) | | The internet intervention was SupportBack. This app was designed to assist people to manage their LBP and support appropriate engagement in physical activity. |
| | | | 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 primary outcomes of the study were the feasibility of the trial design. This included ability to recruit (both participants and GP practices), adherence to the SupportBack internet intervention, and retention at follow up. |
| | | | The study also reported health-economic outcome measures. These included: |
| | | | Total primary care costs of £96, £85 and £108 per person in the usual care alone, internet intervention plus usual care and internet intervention plus physiotherapist support, respectively |
| | | | Total secondary care cost of £175, £191 and £198 per person in the usual care alone, internet intervention plus usual care and internet intervention plus physiotherapist support, respectively |
| | | | Total back pain specific cost of £116, £92 and £228 per person in the usual care alone, internet intervention plus usual care and internet intervention plus physiotherapist support, respectively |
| | | | Overall 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. It also showed the health economic cost outcome data may reduce healthcare resource use for LBP. |

| Study ID | Title | Study type | Narrative summary |
|--|---|--|--|
| | | | The study had limitations given it is only a feasibility trial, with a small sample size, meaning the cost outcomes are uncertain. |
| getUBetter (Health Innovation Network Unpublished) | getUBetter Evaluation Report | A mixed-methods evaluation | A mixed-methods evaluation was adopted and comprised getUbetter, Wandsworth Clinical Commissioning Group (CCG), St George's University Hospitals NHS Foundation Trust, Digital Health.London, University of West of England, and the Health Innovation Network. |
| | | | Health resource utilisation was determined by analysing primary care data. It compared resource use of people with LBP who used getUBetter with the resource use of non-users with LBP. |
| | | | HCRU outcome data for the trial included: |
| | | | |
| | | | There were important limitations to the analysis. The trial was very underpowered, with less than people reported in the results for getUBetter for the above outcomes. Although all those with getUBetter had non-specific LBP, the standard care group were a mix of different types of MSK pain. This was only an early study, so the resource use outcomes should be interpreted with caution. This study has also not been peer-reviewed. |
| Hinge (Optum 2022) | Hinge Medicare Cost and Utilization Study | Cost and utilisation study/retrospective | A cost and utilisation study was conducted to assess the impact of the Hinge digital self- management app on HCRU for people with chronic MSK pain in the US. |
| | | cohort study | The study adopted a retrospective cohort study design. Existing data was gathered from study participants who had met the inclusion criteria. This included being age 65 and older, being Medicare FFS beneficiaries and not having used medical care for their MSK condition in the past 12 months. |
| | | | The control group included those who had started physical therapy (back, knee, shoulder, hip, neck) between 2017 to 2020, whereas the Hinge group were enrolled on the Hinge |

| Study ID | Title | Study type | Narrative summary |
|---------------------|--|---|---|
| | | | app and had completed one exercise session or accessed one educational article from 2017 to 2020. |
| | | | The control group of the study was a cohort of people who did not use the Hinge Health application, where baseline characteristics were matched to those in the intervention group (n=467). |
| | | | 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. |
| | | | Economic outcomes and HCRU costs reported in the study include: |
| | | | Total MSK cost of care for the Hinge Health group of \$42.70 per member per month (PMPM) |
| | | | Total control group cost of care \$221.27 PMPM |
| | | | Hospital inpatient and outpatient cost of \$42.70 for the Hinge Health group |
| | | | Hospital inpatient and outpatient services cost of £263.97 for the control group |
| | | | It is important to note that this study was taken from a US healthcare perspective, which differs considerably from NICE's perspective (insurance-based compared with universal healthcare). This study has also not been peer reviewed. |
| (Hinge Health 2022) | Digital musculoskeletal impact on | Cost and utilisation pre/post longitudinal cohort | A cost and utilisation study was conducted to assess the impact of the Hinge digital self- management app on HCRU for people with chronic MSK pain in the US. |
| | medical claims: 136 employer study | study | The study adopted a retrospective cohort study design. Existing data was gathered from study participants who had met the inclusion criteria. This included being between the ages of 18-64 years old, be continuously enrolled in a health plan 12 months before and after starting Hinge Health/index event, and had at least one nonsurgical, MSK-specific medical |

| Study ID | Title | Study type | Narrative summary |
|-----------------------------|-------|-------------------------------|--|
| | | | care claim in the 12 months before starting the Hinge Health chronic programme or before the index event. |
| | | | Furthermore, if they were in the Hinge Health group then they must have 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. If they were in the control group they must have had a physical or occupational therapy or provider visit for back, knee, shoulder, hip, or neck pain in January 2020 through October 2020. |
| | | | 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. |
| | | | Economic outcomes and HCRU costs reported in the study include: |
| | | | Total Hinge Health group MSK cost of care \$483.94 per person per year Total control group MSK cost of care \$2,870.96 per person per year |
| | | | Total lower MSK claims reduction of \$2,387.02 between Hinge Health group and control group |
| | | | It is important to note that this study was taken from a US employer and healthcare perspective, which differs considerably from NICE's perspective (insurance-based compared with universal healthcare). All participants in this study are employed, which is not reflective of the full MSK population. This study has also not been peer reviewed. |
| (Validation Institute 2023) | 2023 | Cost and utilisation pre/post | A cost and utilisation study was conducted to assess the impact of the Hinge Health digital self-management app on HCRU for people with chronic MSK pain in the US. |

| Study ID | Title | Study type | Narrative summary |
|--------------------|--|--------------------------------------|--|
| | Validation Report. Review for: Hinge Health. | longitudinal cohort study | The inclusion criteria were that Hinge Health users were included if they used the Hinge Health programme in 2018 and could be matched to a similar non-user. No detail is provided on the 'non-users'. |
| | | | 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. |
| | | | Economic outcomes and HCRU costs reported in the study include: |
| | | | Over 2 years, MSK medical claims spend was \$2244 less per Hinge Health participant compared to the matched control group. |
| | | | In year 2, there were 68.7% fewer Hinge Health participants undergoing invasive procedures than the matched control group. |
| | | | It is important to note that this study was taken from a US employer and healthcare perspective, which differs considerably from the UK's (insurance-based vs. universal healthcare). All participants in this study are employed, which may not be reflective of the full MSK population. This study has also not been peer reviewed. |
| Pimm et al. (2017) | An evaluation of a web-based pain management programme "Pathway through Pain" | A pre/post-test design evaluation | A poster that highlighted the results from a pre/post-test study of the digital pain management pathway (PMP) "Pathway through Pain" Vs TAU. The study defined TAU as those who received standard or conventional care but did not specify what treatment is given. |

| Study ID | Title | Study type | Narrative summary |
|-----------------|--|--------------------------------------|---|
| | | | 1,062 people with chronic pain who had been referred by physiotherapists between 2012 and 2016 were considered for inclusion in the study. A screening process by clinical psychologists found 87% of these referrals were suitable for PMP. |
| | | | However, participant numbers for the final analysis on healthcare costs were far lower, n=90 for TAU and n=100 for Pathway through Pain. |
| | | | Paired samples t-tests were used to assess the different HCRU between comparator and intervention groups. |
| | | | Economic outcomes and HCRU costs reported in the study included: |
| | | | TAU Group had a pre-intervention average cost of £572.25 and a post-intervention cost of £699.26, a difference of £127.01 |
| | | | Pathway through Pain group had a pre-intervention average cost of £925.49 and a post-intervention cost of £510.71, a difference of -£414.77. |
| | | | This study was only a published abstract, so the full study has not been peer reviewed. |
| Pimm T J (2019) | An evaluation of a digital pain management programme: | A pre-post observational study | A between-groups comparison study was conducted to examine health care usage differences between individuals engaged in a digital PMP "Pathway through Pain" and those not engaged. |
| | clinical effectiveness and cost savings | | The study had recruited participants with chronic pain via physiotherapist referral within an MSK service or pain management service. A clinical psychologist had then assessed the suitability of Pathway through Pain for those referred. Out of the original 837 people referred, 12% were found to be unsuitable for Pathway through Pain. Of the suitable group, 59% accessed Pathway through Pain (engaged group) and 41% (300) did not access Pathway through Pain (non-engagers). |
| | | | The study had collected the difference in costs related to HCRU for the year before referral and the year after referral for the engaged and non-engaged group. These results had |

| Study ID | Title | Study type | Narrative summary |
|----------|-------|------------|--|
| | | | shown a reduction in HCRU costs for those engaged compared with an increase in HCRU with the non-engaged group: |
| | | | The engaged group had £-14.45, £-118.13, £-20.35 and £-152.93 for A&E difference, inpatient difference, outpatient difference and overall difference, respectively. |
| | | | The non-engaged group had £-9.93, £47.03, £50.27 and £87.37 for A&E difference, inpatient difference, outpatient difference and overall difference, respectively. |
| | | | Limitations of the study are that the study participants are not restricted to LBP as it included individuals with chronic pain. Additionally, a high dropout rate and non-randomised comparison group may have had an impact on any conclusions drawn from the study. |

Key: A&E – Accident and emergency, AqoL-6D – Assessment of quality of life – 6D scale, CBP – Chronic back pain; CBT – Cognitive behavioural therapy, CCG – Clinical commissioning group, DTC – Digital therapeutic care, F2F – Face-to-face, FFS – Fee-for-service, HCRU – Health care resource utilization, ICER – Incremental cost-effectiveness ratio, ICUR – Incremental cost-utility ratio, IMI – Internet and mobile-based intervention, MSK – Musculoskeletal, PMP – Pain management pathway, PMPM – Per member per month, PSA – Probabilistic sensitivity analysis, QALY – Quality-adjusted life year, RCT – Randomised controlled trial, TAU – Treatment as usual, Vs – Versus.

8.2 Economic modelling

The primary purpose of this analysis was to assess whether it is plausible that using digital technologies for managing non-specific LBP is a cost-effective intervention when used alongside standard care for people aged 16 years and over who are eligible for digital management. The secondary aim of the analysis was to identify the value of future research, understand the likely key drivers of the results, and highlight the current evidence gaps.

A simple cost-utility model was designed to capture the potential benefit that could be provided from these technologies over a 1-year time horizon. There is heterogeneity in the types of digital technologies, the type of pain they are used for (acute and chronic), and their placement in the care pathway. Some technologies do not have any data or evidence to present, while others have only collected limited evidence so far. Hence, the evaluation is not expected to capture one base case that represents all digital technologies for non-specific LBP. However, the model can be used to highlight the potential impact or value of digital technologies for non-specific scenarios, including pricing structure or more specific elements of the applications. The EAG considers that the cost-utility model can provide an indication of the direction of the results, given the base case assumptions. Therefore, this should be useful for decision-makers to evaluate the potential of digital technologies to support self-management of LBP.

The model is not representative of ACT for PAIN given the lack of economic evidence associated with ACT and psychological-specific treatments and where these fit in the pathway. Additionally, no evidence was provided by the company of technology's effectiveness (National Institute for Health and Care Excellence 2020a). Due to the limited data, the model focuses on physiological interventions rather than psychological (or technologies which have at least a physiological component). ACT for PAIN is therefore discussed further in section 8.4.

8.2.1 Population

The EAG considered people (aged 16 or over) with either acute or chronic non-specific LBP that are eligible for digital technology management. This is in line with the NICE final scope. Studies that may captured a mix of acute and chronic LBP, as well as specific acute and chronic LBP evidence, were considered when developing the model. Previous studies do not specify whether the technology was used in either of these sub-populations, so a pragmatic approach was taken to analysing the potential impact on subgroups. Some evidence with mixed MSK conditions has been considered by the EAG for the model given the lack of LBP-specific evidence. The generalisability of evidence for MSK pain in relation to solely LBP should be considered by decision-makers, while the results of the analysis should be interpreted with caution.

8.2.2 Model structure

The model used by the EAG was a cost-utility model with a 1-year time horizon. The model estimated resource use across the different treatment arms, and then applied costs to the different resource use. QALYs were added into the model based on previous studies, with differences in quality of life tracked over the course of a year. Given the short time horizon and in line with the outcomes captured in the evidence, mortality was not considered in the model. The 1-year time horizon was used because the long-term benefit of treatment was very uncertain; the maximum follow-up of the sourced clinical studies was 9 months. Furthermore, people with LBP, particularly those with chronic LBP, are at risk of pain relapses, where future treatment is likely to be sought. Hence, the EAG believed that for this early evaluation, the time horizon should be limited to 1 year. Cost-effectiveness was evaluated using a cost-effectiveness threshold of £20,000 per QALY. Given that this is an early evaluation with a high degree of uncertainty, presented results were not compared with NICE's upper cost-effectiveness threshold of £30,000 per QALY.

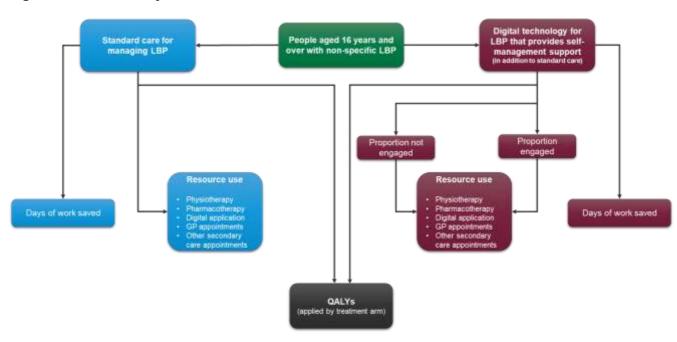
The model structure was limited by the amount and type of data available, and assumptions have been made to populate it. The model should therefore be seen as an initial exploration of the economic impact of digital technologies that provide self-management support, alongside standard care, for the treatment of non-specific LBP.

The model captured different resource use that can be attributed to care associated with acute or chronic LBP. In the base case, the modelling approach took the perspective of the NHS and personal social services. However, a wider societal perspective is taken as part of scenario analysis. In this wider perspective, the impact of days of work saved is also included in the model. The EAG notes that this should be interpreted with caution, and may introduce perverse incentives into decision-making, given there are reasons people may not work, such as they are retired or full-time parents. This is included since it is listed as an outcome in the final NICE scope.

The key aspect of the base case model was to capture key resource use based on the available evidence and clinical assumptions. This includes physiotherapy, GP appointments and other secondary care appointments, as well as any impact on pharmacotherapy. This resource use may not be exhaustive, especially given the heterogeneity of standard care that may be person specific. The model does not have a specific placement in the clinical pathway due to the limited evidence available to populate the model. While different placements in the care pathway may lead to different reported outcomes (which would lead to differences in model inputs), available evidence does not specify where technologies are used. For instance, when used in primary care for new presentations, it may be healthier populations using the technology with less severe LBP, whereas if it is placed in secondary care, people with less severe LBP may be screened out. Differences in LBP severity or other characteristics may impact the effectiveness of where the technology is placed in the pathway.

Potential impacts on HRQoL, in the form of EQ-5D-3L, were captured based on the clinical evidence to calculate the cost-effectiveness of the digital technologies alongside standard care. It is understood that there are questions around whether using EQ-5D-3L directly is sensitive enough to capture changes in pain. However, as no pain-specific measure could be mapped onto EQ-5D, or provide a HRQoL value, EQ-5D-3L was used for this early evaluation. If it is not sensitive enough to capture HRQoL, this will mean the model results are expected to be a more conservative estimation of the

impact of digital technologies for non-specific LBP. The HRQoL in the model was not defined by health states. Instead, it was modelled using the average quality-of-life data as part of the cost-utility model framework. Effectiveness of the digital technologies were captured through potential reductions in resource use when people engaged with the technology, as well as differences in QALYs captured within the model. A state-driven model is expected to be useful as more evidence is collected. This is detailed in section 10.3. The cost-utility model diagram is presented in Figure 8.1.





Outcomes from the model included incremental cost between treatment arms, breakdown in resource use, ICER, incremental net monetary benefit (NMB) and incremental net health benefit (NHB). Deterministic sensitivity analysis (DSA) was conducted using a tornado diagram, which highlights the key drivers of the model results. Economically justifiable price (EJP) was also calculated as part of the DSA. EJP should be interpreted with extreme caution, given that the results of the analysis are designed to be indicative. Therefore, the true value is likely to be very uncertain and heterogenous across different digital technology providers. Probabilistic sensitivity analysis (PSA) was also conducted, with 1,000 simulations of the model run (enough for the results to stabilise), and the results averaged. Where possible, confidence intervals or appropriate ranges (based on clinical experts or ranges from company evidence) were used to inform parameter uncertainty. Where no appropriate ranges could be determined, a standard error of 20% of the mean was assumed to inform parameter uncertainty, providing this appeared to capture appropriate ranges. Although this is an arbitrary variation, the EAG notes this still allows for greater understanding of the key drivers. Future modelling should look to determine appropriate confidence intervals for these inputs.

Although a probabilistic base case is preferred for health technology assessment, a deterministic base case was used given that this is an early evaluation and a simple model. The results of the deterministic and probabilistic base case are very similar, so the EAG does not expect this to impact any outcomes of the analysis. Only utilities used in the economic model reported standard errors to vary in PSA. Therefore, PSA may not be useful due to the unknown uncertainty among the inputs.

Value of information (VOI) analysis was not conducted as part of this analysis due to the limited data associated with LBP across the technologies relevant for costeffectiveness. VOI would be most useful when more robust data has been collected at the point of decision making. Over half of the data in the EAG model is based on assumptions or data that is not specifically associated with LBP. The model structure is simplified to account for the lack of data and focuses on the data that is available. Therefore, the EAG believe it would not be useful to conduct VOI given that there is not a clear idea of confidence interval ranges for specific parameters.

8.2.3 Assumptions and limitations

A number of assumptions were required to produce the cost-utility model using the available data. These assumptions may not completely reflect the differences in the various digital technologies, or different treatment pathways. These assumptions are discussed in

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Table 8.2: Assumptions and limitations of the current model

| Assumption | Discussion |
|--|--|
| The model does not fully capture differences in safety between digital technologies for non- specific LBP and standard care. Hence, one key assumption is that any safety feature built into the app is assumed to be 100% effective. | One key issue raised by clinical experts was a 'safety net' feature, to make sure technologies are able to identify those people who may have a specific cause of their back pain, rather than a non-specific one. This is not captured within the model. These features are not included for every technology and may be less relevant for technologies that are placed along different later parts of the care pathway. For instance, technologies for chronic pain may only be used after 6 months, in which case the risk of a specific condition is expected to be less likely, given there has been more time for investigations. The potential future costs or quality of life impact of missing specific conditions is not included in the model due to the short time horizon and a lack of data required to populate the model. Similarly, the model includes key resource use such as primary and secondary care appointments but does not account for any emergency care or mortality. |
| Costs of the technologies can be scaled down to a per person cost based on GP sizes, ICS sizes, or other metrics used for costing by digital technology companies. | As part of the model, the running cost of the digital technology are captured in the model. These costs vary between companies, with different pricing structures used by different companies. The modelling approach assumes this can be scaled using metrics like GP size or ICS size to derive a common metric per person. GP sizes are likely to vary across the country, meaning that costs may also vary when implementing the different digital technologies. |
| Training and implementation costs are not included in the model base case, as it is currently unclear on what resource use would be required. | Training costs are likely to be minimal, given these are technologies which clinicians can refer people to, so the key training is understanding the usefulness and appropriate times for referral. It is likely that it would take less than half a day for clinicians to be trained on the use of the application, which costed over all the patients they may see for non-specific LBP, is likely to be minimal. Extra resource use may be required if clinicians are required to spend time showing the digital technology to the person. |
| | Implementation costs are more uncertain. No company has detailed the likely implementation costs of imbedding their service within NHS practices. Given the types of technologies, the EAG would expect these to be low. However, a scenario has been included to account for potential implementation costs and the impact it has on the economic results. |
| | Sensitivity and scenario analysis around the cost of the intervention are likely to account for these potential factors on a per person basis. The potential for larger upfront costs may have to be considered for budget purposes of NHS providers. |

| Assumption | Discussion |
|--|--|
| Some data used in the model is not exclusive to non-specific LBP populations. | Due to the limited resource use and quality of life data, gaps in evidence means that mixed population data has been used for the modelling. Where possible, LBP makes up the largest proportion of people in the study (if stratified by pain type). The generalisability of this data to non-specific LBP is uncertain, which is important when interpreting the model results. |
| Outcomes associated with preventing chronic pain at the acute phase is not fully captured in the model. | Although some resource use and quality of life data is captured over time where available, the potential of technologies preventing chronic pain at the acute phase may lead to benefits and longer-term outcomes that are not captured in the model. If digital technologies do prevent the development of chronic pain, then the results of this analysis may be a conservative estimation of the impact of introducing digital technologies for LBP. |
| | One company has provided evidence for reducing the development of chronic back pain in people with acute LBP, in the US, although the longer-term outcomes associated with this are not collected and this evidence was considered to be not generalisable to the UK (Hong M 2022). |
| Long-term outcomes of treatment are not captured. The model uses a time horizon of 1 year due to short follow up in the available clinical evidence. | People who undergo treatment may realise benefits, such as improved quality of life or reduction in healthcare resource use over time, after treatment has already subsided (if the treatment has been effective in managing their pain). Currently, there is limited evidence with long-term follow up, so the impact beyond 1 year is uncertain. The EAG notes that some benefits may occur after 1 year, meaning a 1-year time horizon could be considered more conservative for evaluating the potential impact of digital technologies for non-specific LBP. |
| The impact of waiting time is not explicitly captured in the model | Reduced waiting time is one of the key value propositions for introducing digital technologies for non-specific LBP. However, the resource use and quality of life associated with reducing waiting time is expected to be already captured within the evidence used to populate the model. By factoring in wait times directly into the model, the model may double count the potential benefits of the digital technologies. Hence, it is discussed narratively in section 8.4, while it is acknowledged some of the potential benefit of a reduced wait time is already captured. |
| Healthcare appointments and overall prescriptions are scaled in the same way regardless of chronic or acute pain. This is expected to overestimate the impact in those with acute pain. | Due to a paucity of data, it is not possible to split the resource use data by acute or chronic for healthcare appointments or prescriptions given. As a result, these have been scaled in the same way to estimate the resource use for a year (given some of those with acute pain will go on to develop chronic pain). This is likely to overestimate the resource use for acute pain but is a simplifying assumption due to limited evidence. This can be addressed based on future analysis, as discussed in section 10 and 11. |

| Assumption | Discussion |
|---|--|
| The model does not capture a specific place in the care pathway for digital technologies. | Digital technologies are expected to be used alongside standard care, meaning that other NHS services and treatments are likely to be accessed as well. Furthermore, the evidence currently reported which is used to populate the model is limited and does not specify where in the care pathway the technology was placed. The model structure is not likely to change if the digital technologies are placed at different points in the care pathway, although, the effectiveness of the digital technologies may differ depending on the placement in the pathway. There may also be a change in baseline characteristics of people being treated in different pathways which will have an impact on the outcomes. However, due to the limited evidence available, it is not known how different placements of the technologies will impact treatment outcomes. |

Key: EAG – External assessment group, ICS – Integrated care system, LBP – Low back pain.

8.2.4 Model inputs

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 except for the cost of the technologies. A pragmatic approach was taken to populating the model, which included using resource use from studies that used wider populations than non-specific LBP, due to the limited evidence base. Where there was a paucity of data, assumptions have been made that are explained throughout this section and, where possible, clinically verified. The range of values from the company evidence submissions were used as uncertainty intervals for sensitivity analyses where possible.

Set-up inputs

Set-up parameters are detailed in Table 8.3Table 8.3: Population model inputs. In the base case, the model compared digital technologies alongside standard care, with standard care alone, to support self-management of non-specific LBP. Subgroups included acute and chronic LBP.

Resource use

Resource use inputs were primarily derived from company submission documents, such as the getUBetter evaluation report (Health Innovation Network Unpublished). Primary care, physiotherapy, secondary care and medication resource use is outlined in Table 8.4, Table 8.5 and Key: EAG – External assessment group, Vs – Versus.

Table 8.6 and Table 8.7, respectively. Resource use is presented for both acute and chronic LBP where differences were sourced. Where they are assumed to be the same, only one value is presented.

Costs

Costs were derived from the company evidence submissions, PSSRU (Jones 2022), the British National Formulary (BNF) (National Institute for Health and Care Excellence 2023) and the National Cost Collection for the 2022 (NHS England 2022) cost year. Device costs, primary care costs, secondary care costs and medication costs are outlined in Table 8.8,

Table 8.9, Key: EAG – External assessment group.

Table 8.10 and Table 8.11, respectively. Where costs differ between acute and chronic

subgroups this is stated in a comment. The base case average cost per person per

year for the digital technologies to support non-specific LBP is £199.21.

Efficacy

Efficacy inputs were derived from company evidence submissions. The proportion engaged with treatment was derived from Bailey et al. (2020), which reported on Hinge. Different company evidence submissions included engagement measured in different ways, such as logging on to the app or downloading the app. Bailey et al. (2020) measured engagement as the proportion of people who completed the digital care program and hence actively engaged in the digital intervention. However, this study was in a population of people with chronic pain only and engagement was assumed to be the same across people with both chronic and acute pain. The proportion engaged, consultation and treatment use reduction, and medication use reduction are outlined in Table 8.12,

Table 8.13 and

Table 8.14, respectively.

Health state utilities

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. Published painmeasuring instruments included Pain Self-Efficacy Questionnaire (PSEQ) (Verdoorn 2021), Fear Avoidance Belief Questionnaire (FABQ) and Roland Morris Disability Questionnaire (RMDQ), amongst others. However, it is difficult to compare the assessment of pain from papers using different pain-measurement instruments, and mapping from the respective pain scores to a utility measurement is challenging. A limitation of the EQ-VAS is that it includes potential biases, such as scaling bias (Weinstein M C 2009). The sensitivity of EQ-5D for eliciting pain scores is also documented within the literature (Whynes D K 2013). EQ-5D utility scores are outlined in Table 8.15 and EQ-VAS utility scores are outlined in

Table 8.16.

Return to work

Absenteeism may be a potential driver of wider societal costs associated with acute, and to a greater extent, chronic LBP. Therefore, a scenario was conducted to understand the potential impact digital technologies may have on absenteeism. General population earnings, the number of days missed due to LBP, and the cost of absenteeism due to LBP are outlined in Table 8.17, Table 8.18 and Table 8.19, respectively.

Set-up inputs

Table 8.3: Population model inputs

| Variable | Value | Source | EAG commentary of availability, quality, reliability and relevance of the source/s |
|-----------------------------------|-------|----------------------|--|
| 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. |

Key: LBP - Low back pain, RCT - Randomised controlled trial.

Resource use inputs

 Table 8.4: Primary care resource use per year

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s | | |
|--------------------------------|---------------|--|--|--|--|
| | Standard care | | | | |
| GP face-to-face appointment | | getUBetter evaluation report (Health Innovation Network Unpublished) | This was scaled to 1- year resource use, assuming the relative resource use each month remains constant. | | |

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--------------------------------|-------|--|---|
| | | | This period was during the COVID-19 pandemic and the numbers may not reflect a post-pandemic world. |
| | | | Acute and chronic inputs were assumed equal. |
| Prescription per consultant | | getUBetter evaluation report (Health Innovation Network Unpublished) | . This was scaled to 1-year resource use, assuming the relative resource use each month remains constant. This period was during the COVID-19 pandemic and the numbers may not reflect a post-pandemic world. Acute and chronic inputs were assumed equal. |

Key: EAG – External assessment group.

Table 8.5: Physiotherapy referrals per year

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--|--------------|--|---|
| | | Standard of | care |
| Frequency of physiotherapy referrals | | getUBetter evaluation report (Health Innovation Network Unpublished) | his was scaled to 1-year resource use, assuming the relative resource use each month remains constant. This period was during the COVID-19 pandemic and the numbers may not reflect a post-pandemic world. |
| Average number of physiotherapy appointments | 2.50 Acute | Assumption | Acute and chronic inputs were assumed equal.Based on communication with a consultant MSK physiotherapist via email on 24/07/23.There is no difference in the average number of physiotherapy appointments for acute and chronic between standard care and the |
| appointments | 4.50 Chronic | | intervention. |
| Proportion of physiotherapy referrals that are one-to-one Vs group sessions | 50% | Assumption | There was no clinical evidence to determine the different types of physiotherapy a person may receive, so a naïve assumption was made to split sessions equally between one-to-one and group physiotherapy. |

Key: EAG – External assessment group, Vs – Versus.

Table 8.6: Secondary care resource use per year

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s | |
|--|-------|--|--|--|
| | | | Standard care | |
| | | getUBetter evaluation report (Health Innovation Network Unpublished) | Secondary care appointments were assumed to be equal to physiotherapy referrals. | |
| Secondary care appointments | | | This was scaled to 1-year resource use, assuming the relative resource use each month remains. | |
| appointments | | | This period was during the COVID-19 pandemic and the numbers may not reflect a post-pandemic world. | |
| | | | Acute and chronic inputs were assumed equal. | |
| Emergency appointment related to LBP | 0.00 | Assumption | A conservative assumption was made that there would be no emergency appointments related to LBP for people with either acute or chronic LBP. | |

Key: EAG – External assessment group, LBP – Low back pain.

Table 8.7: Medication use prescriptions per year

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|---|---------------|--|--|
| | | Standa | ard care |
| | Acute 2.25 | | Each pack contains 100 tablets, with a maximum of 8 tablets to be consumed per day (4g a day). |
| | 2.25 | | Time each pack lasts = 100/8 = 12.5 days. |
| Paracetamol | | BNF (National Institute for | Acute: Paracetamol to be prescribed for 28 days (4 weeks), as per |
| (500mg, pack size 100) | | Health and Care Excellence 2023) and assumption | communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| | Chronic 29.20 | | Chronic: The above has been scaled up to 1 year (paracetamol assumed to be taken continuously over one year). |
| | Acute | BNF (National Institute for | ce maximum of 3 days for both codeine and co-codamol. Assumed one full |
| Codeine (30mg, pack | 1.00 | Health and Care Excellence – 2023) and NG193 (National Institute for Health and Care | |
| size 28) | Chronic | | course over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| | 0.00 | Excellence 2020a) | |
| | Acute 1.00 | BNF (National Institute for Health and Care Excellence 2023), NG193 (National Institute for Health and Care Excellence 2020a) and assumption | Chronic: Assumed people with chronic LBP are not prescribed opioids in the base case due to opioids not being recommended for non-specific chronic pain. |
| Co-codamol (30mg/500mg tablets, pack size 100) | Chronic 0.00 | | |

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--|--------------|--|--|
| | | | Acute: BNF recommendation for pain is maximum of 400mg per day. 50mg tablets (8 per day). Time each pack lasts = 100/8 = 12.5 days. Assumed to take over 28 days (4 |
| Tramadol (50mg, | Acute 2.25 | BNF (National Institute for Health and Care Excellence | weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| pack size 100) | Chronic 0.00 | 2023), NG193 (National Institute for Health and Care Excellence 2020a) and assumption | Chronic: Assumed people with chronic LBP are not prescribed opioids in the base case due to opioids not being recommended for non-specific chronic pain. |
| | Acute 1.00 | | Acute: BNF recommendation for pain is a maximum of 400mg per day. |
| | | BNF (National Institute for Health and Care Excellence 2023) NG193 (National Institute | 5mg tablets every 4-6 hours but can vary depending on pain. |
| Oxycodone (5mg, | | | Assumed one full course over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| pack size 56) | | Chronic: Assumed people with chronic LBP are not prescribed opioids in the base case due to opioids not being recommended for non-specific chronic pain. | |
| Buprenorphine (200mcg, pack size 50) | Acute 2.25 | | Acute: BNF recommendation for pain is 200–400 micrograms every 6–8 hours. If assuming a higher dose, 1600 micrograms per day (8 tablets). |
| | | BNF (National Institute for Health and Care Excellence 2023), NG193 (National Institute | Assumed to take over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| | Chronic 0.00 | for Health and Care Excellence 2020a) and assumption | Chronic: Assumed people with chronic LBP are not prescribed opioids in the base case due to opioids not being recommended for non-specific chronic pain. |

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|----------------------------------|---------------|--|--|
| | Acute 1.48 | | BNF recommendation for acute pain. |
| | Acule 1.40 | | 5mg every 4 hours. 30mg max dose per day, which is 3 tablets per day. |
| | | BNF (National Institute for | Time each pack lasts = 56/3 = 18.6 days. |
| Morphine (10mg, pack size 56) | | Health and Care Excellence 2023), NG193 (National Institute for Health and Care Excellence | Acute: Assumed to take over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| | Chronic 0.00 | 2020a) and assumption | Chronic: Assumed people with chronic LBP are not prescribed opioids in the base case due to opioids not being recommended for non-specific chronic pain. |
| | Acute 2.00 | | BNF recommendation for pain is 400mg maintenance 3 times per day. 6 tablets per day. |
| | | | Time each pack lasts = 84/6 = 14 days. |
| Ibuprofen (200mg | | BNF (National Institute for | |
| tablets, pack size 84) | Chronic 26.00 | Health and Care Excellence 2023) and assumption | Acute: Assumed to take over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| | | | Chronic: The above has been scaled up to 1 year (ibuprofen assumed to be taken continuously over one year). |
| | Acute 1.97 | | BNF recommendation for pain is 250 mg every 6–8 hours as required. 4 tablets per day. |
| | | | Time each pack lasts = 56/4 = 14 days each. |
| Naproxen (250mg | | BNF (National Institute for | |
| tablets, pack size 56) | | Health and Care Excellence 2023) and assumption | Acute: Assumed to take over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. |
| | Chronic 25.60 | | Chronic: The above has been scaled up to 1 year (naproxen assumed to be taken continuously over one year). |

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| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--|---------------|---|---|
| Celecoxib (100mg capsules, pack size 60) | Acute 1.85 | BNF (National Institute for Health and Care Excellence 2023) and assumption | BNF recommendation for pain and inflammation in osteoarthritis is 200 mg twice daily. 4 tablets per day. |
| | Chronic 24.00 | | Time each pack lasts = 60/4 = 15 days. Acute: Assumed to take over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. Chronic: The above has been scaled up to 1 year (celecoxib assumed to be taken continuously over one year). |
| Etoricoxib (30mg tablets, pack size 28) | Acute 1.97 | BNF (National Institute for Health and Care Excellence 2023) and assumption | BNF recommendation for pain and inflammation in osteoarthritis is 60 mg once daily. 2 tablets per day. Time each pack lasts = 28/2 = 14 days. |
| | Chronic 25.60 | | Acute: Assumed to take over 28 days (4 weeks), as per communication with Ben Wanless (Consultant MSK physiotherapist) via email, 24/07/23. Chronic: The above has been scaled up to 1 year (etoricoxib assumed to be taken continuously over one year). |

Key: BNF – British National Formulary, EAG – External assessment group, LBP – Low back pain, NG193 – NICE guideline 193, MSK – Musculoskeletal.

Cost inputs

Table 8.8: Device costs cost per person per year

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|-------------------------|---------|---|--|
| | | | Elicited from correspondence with getUBetter Ltd and request for information document. |
| | | | Deployment charge per GP practice= Annual charge per adults served= Number of people per GP practice=8,636, Number of adults served per charge= |
| getUBetter | | getUBetter Ltd, NHS Digital (2023); Jordan KP (2014) | (Deployment charge per person/(Number of people per GP practice*Prevalence of LBP in England)+(Annual charge per adults served/(number of adults served per charge*Prevalence of LBP in England)) |
| | | | Number of people per GP practice sourced from NHS Digital. |
| | | | Prevalence of LPB = 5.87% sourced from Jordan et al 2014 (see Table 8.3). |
| | | - | Cost per person per year = from Hinge Health's request for information document. Converted to GBP: 1 USD = 0.78 GBP, so may not be |
| | | | generalisable to the UK. |
| Hinge | | Hinge | These proportions were elicited from clinical correspondence with Hinge Health. |
| | | | Total weighted cost per year calculated by using the proportion of people with acute and chronic pain (see Table 8.2). |
| Pathway through Pain | | Pathway through Pain | Cost per patient referral obtained via request for information document. |
| selfBACK | £115.57 | Backing self-management physio | Mid-point of 120 to 150 euros per patient taken as 135 euros. Converted to GBP: 1 EUR = 0.86 GP |

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| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|----------------|---------|------------------------|---|
| | | (Mork J P 2020) | |
| SupportBack | £50.00 | Geraghty et al. (2018) | Cost per person of internet intervention plus usual care. Assumed cost in the paper included server provision and website maintenance. £12.50 per 3 months per person. Multiplied by 4 to find annual cost. |
| | | | If physiotherapist support was included as part of the application, the cost increased to ± 50.50 per 3 month and ± 202 per year. |
| Base case cost | £199.21 | | The average cost of all digital interventions (where costs were available). |

Key: EAG – Exploratory assessment group, GBP – Great British Pound, LBP – Low back pain.

Table 8.9: Primary care unit costs

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--|---------|-------------------------|---|
| GP face-to-face appointment | £41.00 | PSSRU 2022 (Jones 2022) | Table 9.4.2: Unit costs for a GP. Per surgery consultation lasting 9.22 minutes (average GP consultation length). Qualification costs included. |
| Prescription costs per consultant | £29.00 | PSSRU 2022 (Jones 2022) | Table 9.4.2: Unit costs for a GP. Prescription costs per consultation (actual cost). |
| Physiotherapist one-to- one session | £144.00 | PSSRU 2022 (Jones 2022) | Table 6.1.1: Unit costs for hospital services. COMMUNITY SERVICES, average cost per physiotherapy session. |
| Physiotherapist group session | £92.00 | PSSRU 2022 (Jones 2022) | Table 6.1.1: Unit costs for hospital services. COMMUNITY SERVICES, average cost per physiotherapy session. |

Key: EAG – External assessment group.

Table 8.10: Secondary care unit costs

| Parameter | Value | Source EAG commentary on availability, quality, reliability and relevance of the source/s | |
|--|---------|---|--|
| Secondary care appointments | £98.54 | NHS cost collection 2021/22 (NHS England 2022) | Outpatient care, physiotherapy service (service code 650), face-to-face. Weighted average of consultant and non-consultant led appointments |
| Emergency appointment related to LBP | £503.44 | NHS cost collection 2021/22 (NHS England 2022) | The weighted average of all non-elective short stay (NES) and daycase (DC) costs associated with Musculoskeletal signs or symptoms (HD26D-G). |

Key: DC – Day case, EAG – External assessment group, LBP – Low back pain, NES – Non-elective short stay.

Table 8.11: Medication costs

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s |
|--|-------|---|--|
| | · | Cost per pa | ack |
| Paracetamol (500mg, pack size 100) | £1.34 | BNF 2023 (National Institute for Health and Care Excellence 2023) | Mandanol. NHS indicative price. Caplets. |
| Codeine (30mg, pack size 28) | £1.06 | BNF 2023 (National Institute for Health and Care Excellence 2023) | Alliance Healthcare Ltd Drug tariff price. Tablets. |
| Co-codamol (30mg/500mg tablets, pack size 100) | £4.03 | BNF 2023 (National Institute for Health and Care Excellence 2023) | A A H Pharmaceuticals ltd. Drug tariff price. Caplets. |
| Tramadol (50mg, pack size 100) | £2.90 | BNF 2023 (National Institute for Health and Care Excellence 2023) | A A H Pharmaceuticals ltd. Drug tariff price. Capsules. |

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| Oxycodone (5mg, pack size 56) | £5.15 | BNF 2023 (National Institute for Health and Care Excellence 2023) | G.L. Pharma UK Ltd. Drug tariff price. Tablets. |
|--|-------|---|---|
| Buprenorphine (200mcg, pack size 50) | £5.04 | BNF 2023 (National Institute for Health and Care Excellence 2023) | Eumedica Pharmaceuticals AG. Drug tariff price. Tablets. |
| Morphine (10mg, pack size 56) | £5.31 | BNF 2023 (National Institute for Health and Care Excellence 2023) | Napp Pharmaceuticals Ltd. Drug tariff price. Tablets. |
| lbuprofen (200mg, pack size 84) | £3.12 | BNF 2023 (National Institute for Health and Care Excellence 2023) | Milpharm Ltd. Drug tariff price. Tablets |
| Naproxen (250mg, pack size 56) | £1.09 | BNF 2023 (National Institute for Health and Care Excellence 2023) | A A H Pharmaceuticals Ltd Drug tariff price. Tablets. |
| Celecoxib (100mg, pack size 60) | £5.32 | BNF 2023 (National Institute for Health and Care Excellence 2023) | Dawa Ltd Drug tariff price. Capsules. |
| Etoricoxib (30mg tablets, pack size 28) | £2.29 | BNF 2023 (National Institute for Health and Care Excellence 2023) | A A H Pharmaceuticals. Drug tariff price. |

Key: BNF – British National Formulary, EAG – External assessment group.

Efficacy inputs

Table 8.12: Proportion engaged

| Parameter | Value | Source | Comment | |
|--|-------|----------------------|---|--|
| | | | Table 2. 'Completers' proportion of total back pain population, 4,676 / 6,468 = 72.29% | |
| Digital technologies for non-specific LBP | 72.3% | Bailey et al. (2020) | The paper includes participants with chronic knee or back pain, not solely LBP. We have assumed the proportion engaged is equal between both people with chronic and acute. This paper is based in the US, and therefore may not be generalisable to the UK. | |

Key: LBP - Low back pain, US - United States, UK - United Kingdom.

Table 8.13: Consultation and treatment use reduction

| Parameter | Value | Source | Comment |
|-----------------------------------|-------|--|---|
| GP face-to-face appointment | | getUBetter evaluation report (Health Innovation Network Unpublished) | |
| Physiotherapist referrals | | getUBetter evaluation report (Health Innovation Network Unpublished) | |
| Prescription costs per consultant | | getUBetter evaluation report (Health Innovation Network Unpublished) | Assumed to be the same as the reduction in physiotherapy referrals. |

| Secondary care appointments | | getUBetter evaluation report (Health Innovation Network Unpublished) | This is assumed to be the same reduction as physiotherapy referrals. |
|--|------|--|--|
| Emergency appointment related to LBP | 0.0% | Assumption | Assumed that there will be no emergency appointments related to LBP |

Key: LBP – Low back pain.

Table 8.14: Medication use reduction

| Parameter | Value | Source | Comment |
|-------------|-------|--|--|
| Paracetamol | | act Pottor evaluation report | |
| Opioids | | getUBetter evaluation report (Health Innovation Network | |
| NSAIDs | | Unpublished) | Only medications related to backpain were included, such as paracetamol, ibuprofen, naproxen, co-codamol and tramadol. |

Key: NSAID – Non-steroidal anti-inflammatory drug.

Health state utilities inputs

Table 8.15: EQ-5D

| Parameter | Value | Source | EAG commentary on availability, quality, reliability and relevance of the source/s | | |
|---------------------------|--|----------------------|--|--|--|
| | Standard care | | | | |
| 3 months | 0.74 | | Table 2. EQ-5D score for usual care (n=229). Acute and chronic take | | |
| 9 months | 0.76 | Sandal et al. (2021) | the same value for each respective time period. The data is scaled up to one year by weighting the QALYs by the number of timepoints recorded. | | |
| Digital technology to sup | Digital technology to support non-specific LBP | | | | |
| 3 months | 0.76 | Sandal et al. (2021) | Table 2. EQ-5D score for intervention arm (n=232). Acute and chronic take the same value for each respective time period. The data is scaled up to one year by weighting the QALYs by the number of timepoints recorded. | | |
| 9 months | 0.78 | | | | |

Key: EAG – External assessment group – EQ-5D – EuroQol 5 dimension, QALY – Quality adjusted life year.

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Table 8.16: EQ-VAS

| Parameter | Value | Source EAG commentary on availability, quality, reliability and relevance of the source/s | |
|-----------|-------|---|--|
| | | Standard c | are |
| 3 months | 0.71 | | Table 2. EQ-VAS score for the control arm (n=229). Acute and chronic take the same value for each respective time period. The data is scaled up to one year by weighting the QALYs by the number of timepoints |
| 9 months | 0.72 | [→] Sandal et al. (2021) | recorded. |
| | | Digital technology to suppo | ort non-specific LBP |
| 3 months | 0.71 | | Table 2. EQ-VAS score for the intervention arm (n=232). Acute and chronic take the same value for each respective time period. The data is scaled up to one year by weighting the QALYs by the number of |
| 9 months | 0.73 | [→] Sandal et al. (2021) | timepoints recorded. |

Key: EAG – External assessment group, EQ-VAS – EuroQol visual analogue scale, QALY – Quality adjusted life year.

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Return to work inputs

Table 8.17: General population earnings

| Parameter | Value | Source | Comment | |
|---------------------------------------|---------|--|--|--|
| Annual earnings of employed adults | £27,756 | Office for National Statistics (2022) | Median gross annual earnings from ONSE ASHE 1997 to 2017 select estimates. | |
| Daily earning for employed adults | £106 | The annual earnings of employed adults/number of working days per year | Calculated by the annual earnings of employed adults / number of working days per year. £27,756 / 260.893 | |

Key: ONS – Office for National Statistics, ONSE ASHE – Office for National Statistics annual survey or houses and earnings.

8.3 Results from the economic modelling

Exploratory results from the cost-utility model are presented in sections 8.3.1 to 8.3.3. Due to the heterogeneity across the digital technologies and limited evidence to populate the economic model, the base case is designed to represent an indicative average, rather than a definitive representation of every digital technology for nonspecific LBP.

Under the base case assumptions, the deterministic base case model results suggest that digital technologies for non-specific LBP, used alongside standard care, are costeffective compared with standard care alone. The technologies are estimated to reduce healthcare costs and increase quality of life, resulting in a dominant ICER and positive incremental NMB and NHB. The cost breakdown in Table 8.19**Table 8.19: Cost breakdown per person** suggests that the costs saved from primary care, secondary care and reduction in medications outweigh the costs of using the digital technologies.

| | Digital technologies for non-specific LBP* | Standard care | Incremental |
|---------------------|--|---------------|-------------|
| Cost per person | £560 | £644 | -£84 |
| QALYs per person | 0.76 | 0.75 | 0.01 |
| ICER | Dominant | | |
| NMB | £373 | | |
| NHB | 0.02 | | |

Table 8.18: Deterministic base case results

Key: ICER – Incremental cost-effectiveness ratio, LBP – Low back pain, NMB – Net monetary benefit, NHB – Net health benefit, QALY – Quality adjusted life year. *Alongside standard care.

Table 8.19: Cost breakdown per person

| | Digital technologies for non-specific LBP* | Standard care | Incremental |
|------------------|--|---------------|-------------|
| Technology costs | £199 | £0 | £199 |
| Primary care | £265 | £484 | -£218 |
| Secondary care | £50 | £89 | -£38 |

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| Medications | £45 | £72 | -£27 |
|-------------|------|------|------|
| Total | £560 | £664 | -£84 |

Key: LBP – Low back pain.

*Alongside standard care.

8.3.1 Scenario analyses

Given the potential variation in digital technologies for non-specific LBP, such as pricing, and the uncertainty in input values due to limited evidence, a range of scenarios were considered. The scenarios relate to the base case population (a mix of acute and chronic pain) unless otherwise stated. These are described and reported in Table 8.20.

| Table 8.20: | Scenario analyses for hospital inpatient comparator |
|-------------|---|
| | |

| Scenario analyses description | EAG base case description | Incremental cost | NMB |
|---|---|------------------|-------|
| EAG base case | | -£84 | £373 |
| Resource use is not extrapolated up to a 1-year time period | Resource use is taken directly from the study, and not extrapolated to a 1- year time period, despite being only 8 months follow-up | £1 | £88 |
| Acute pain subgroup only | 100% of the cohort entering the model experience acute pain. Inputs (where available) only reflect acute populations. | -£112 | £401 |
| Chronic pain subgroup only | 100% of the cohort entering the model experience chronic pain. Inputs (where available) only reflect chronic pain populations. | -£64 | £353 |
| Highest cost of a digital technology | Cost of the digital technology is set to which is the highest cost of the digital technologies included as part of the model in the base case. | £220 | £69 |
| Lowest cost of a digital technology | Cost of the digital technology is set to which is the lowest cost of the digital technologies included as part of the model in the base case. | -£279 | £568 |
| Highest cost of a digital technology (chronic pain only) | Cost of the digital technology is set to , which is the highest cost of the digital technologies included as part of | £389 | -£100 |

| Scenario analyses description | EAG base case description | Incremental cost | NMB |
|--|--|---------------------|------|
| | the model in the base case, for chronic pain only. | | |
| Opioids included in the treatment of chronic pain | Opioids are included in the treatment of chronic pain. Although they are not recommended for chronic pain, clinical experts have detailed that they are still prescribed. | -£100 | £389 |
| Acute pain resource use is scaled to only one month from the studies used to populate the model | Instead of assuming that the resource use is the same between acute and chronic pain (given the study does not state the mix between subgroups), the acute pain resource use is scaled down to only one month of resource use. | -£6 | £295 |
| Acute pain resource use is scaled to only one month from the studies used to populate the model (Acute pain only) | Instead of assuming that the resource use is the same between acute and chronic pain (given the study does not state the mix between subgroups), the acute pain resource use is scaled down to only one month of resource use. | £74 | £215 |
| Acute pain resource use is scaled to only one month from the studies used to populate the model, and the highest cost of the digital | Instead of assuming that the resource use is the same between acute and chronic pain (given the study does not state the mix between subgroups), the acute pain resource use is scaled down to only one month of resource use. | £173 | £116 |
| technology is used (Acute pain only) | Cost of the digital technology is set to which is the highest cost of the digital technologies included as part of the model in the base case, for acute pain only. | | |
| EQ-VAS scores used for utility estimation | Alternative (less robust) quality of life scores used as an estimate for utility for both the digital technologies and standard care. | -£84 | £214 |
| Societal benefit of 5 day working week reduced absenteeism included | Includes non-healthcare benefits. No evidence of absenteeism was identified. A scenario detailing impact of 1 week reduction in absenteeism with digital technologies as a 'what if' scenario. | -£469 | £758 |
| | Based on earnings lost from 1 week of not working. This scenario should be | | |

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| Scenario analyses description | EAG base case description | Incremental cost | NMB |
|---|--|------------------|------|
| | interpreted with caution due to the perverse incentives of focusing on working time, and how this may impact the outcomes of the evaluation. | | |
| Engagement set to 100% for digital technologies | Assume that the quality of life and resource use data already accounts for those engaged or not engaged with the digital technologies. | -£193 | £593 |
| Secondary care appointments removed | Removes all inclusion of secondary care physiotherapy appointments for both the digital technologies and standard care. | -£46 | £335 |

Key: EAG – External assessment group.

Based on the scenarios listed in Table 8.20, all but 1 scenario are plausibly costeffective at a £20,000 per QALY threshold. The remaining scenario changed the direction of the base case results, but only in the chronic pain subgroup. 5 scenarios indicated that the digital technologies used alongside standard care would not be cost saving.

When using the highest-cost digital technology, which has a cost of per person per year, digital technologies used alongside standard care would no longer be cost-saving. The lowest-cost scenario used a cost of

If resource use is not scaled to a 1-year time period, the results are marginally costincurring at £1 per person, but still cost-effective. Other scenarios suggested that when the resource use is scaled down to 1-month, digital technologies may not be costsaving when considering acute pain only. However, the highest-cost digital technologies were still cost-effective at a £20,000 per QALY threshold.

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. However, if the highest-cost device is used for a subgroup of people with chronic pain (**Mathematica**), the cost-effectiveness results would be above a £20,000 per QALY threshold and resulted in an NMB of -£100.

8.3.2 Deterministic sensitivity analysis

One-way sensitivity analysis was conducted on all model parameters. The results of this analysis are presented in a tornado diagram in Figures 8.2 and 8.3. The analysis suggests the key drivers of the model results are the:

- 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.

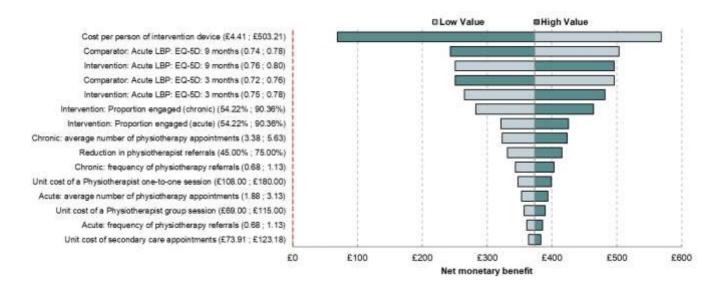
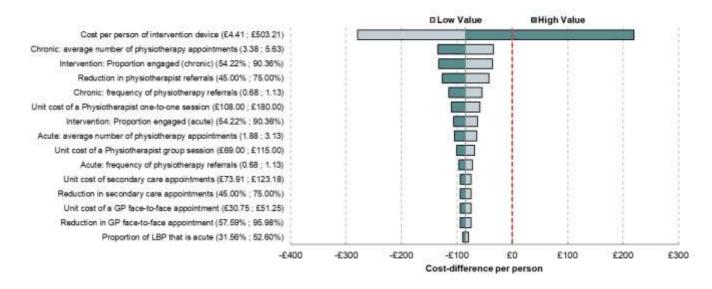


Figure 8.2: Tornado diagram (NMB)

Figure 8.3: Tornado diagram (cost-difference per person)



Additional DSA included EJP analysis with respect to cost-savings. In the base case, the highest price of the digital technologies while still leading to cost-savings was approximately £280 per person. Looking at specifically the acute and chronic subgroups separately, the EJP was approximately £200 and £330 per person respectively. The EJP should be interpreted with caution due to the early nature of the analysis but can be used as an indication of the potential benefits of digital technologies for non-specific LBP.

8.3.3 Probabilistic sensitivity analysis

The PSA indicated similar results to the deterministic base case. The probabilistic incremental cost per person was calculated as -£79, with an incremental QALY of 0.01 per person, and an NMB of £371, based on 1,000 model iterations. A graphical distribution of the results in presented on a cost-effectiveness plane in Figure 8.4. The digital technologies were estimated to be cost-effective in 98.1% of model iterations,

and cost-saving in 76.4% of model iterations. This is highly dependent on the price of the technologies, which ranges widely across the different companies.

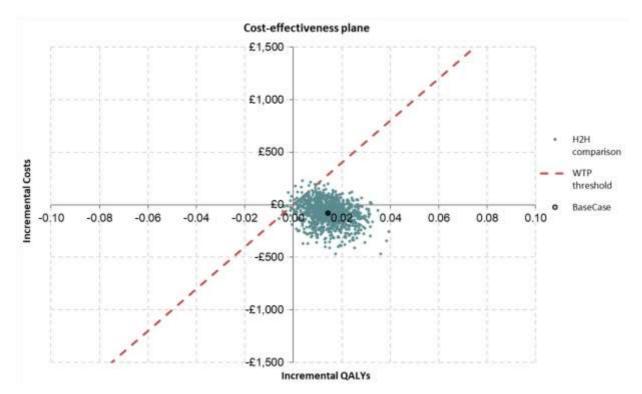


Figure 8.4: Cost-effectiveness plane of PSA

Key: H2H – Head to head, WTP – Willingness to pay.

8.4 Summary and interpretation of the economic modelling

Using the base case assumptions it is estimated to be plausible that digital technologies for non-specific LBP are a cost-effective (and cost-saving) intervention to the NHS. The estimated base case results are not intended to capture every digital technology provider perfectly but are intended to provide an indication of the potential impact from implementing these technologies.

However, the results of this analysis should be interpreted with caution due to the naïve and limited data available. Some companies have no evidence for their technology or have not provided evidence as part of this evaluation, with the model making pragmatic use of the available data. Simplifying assumptions were made throughout the model to provide a useful tool for an early evaluation of digital technologies for non-specific LBP.

Key drivers of the economic results

When the digital technologies were compared with standard care, the key drivers of the results were the impact on HRQoL, the engagement levels associated with the technologies, the reduction in physiotherapy referrals, the potential difference between people with acute or chronic pain, impact of psychological treatments, and the cost of the technologies to the NHS.

Current resource use data is based on limited evidence gathered from studies that were not statistically powered to estimate differences in resource use. One key study used in the model was the

(Health Innovation Network Unpublished). This study was used for reduction in different appointments or referrals and pharmacotherapy prescriptions in the model. The results assume that all technologies will have a similar level of resource use, which may not be the case. Hence, the true impact on resource use is highly uncertain, so the base case results should be interpreted with caution.

The direction of the base case results does not differ by acute or chronic pain population subgroups. However, this is likely a reflection of the lack of evidence to populate the model, given many inputs are the same regardless of pain type, and the resource use data is scaled in the same way for healthcare appointments and number of prescriptions. Hence, the type of pain may be a key driver of the result, especially given that the costing of technologies may also differ by pain type. This is highlighted by the scenario where the highest-cost digital technology for chronic pain produces a result that is not cost-effective at a £20,000 per QALY threshold. Further evidence should be generated on the differences between acute and chronic pain. This is detailed further in section 10.

Technologies specific to psychological treatment aren't represented in the base case model, given the paucity of evidence on resource use or impact across psychological treatments for non-specific LBP.

HRQoL, measured using EQ-VAS or EQ-5D-3L, was presented in the economic evidence to reflect the improvement in quality of life following the use of digital technologies. However, the study that the data in the model was sourced from did not report a statistically significant improvement (Sandal et al. 2021). The estimated differences in quality of life following the use of the digital technology tended to be less than the impact on pain or physical function in clinical studies for non-specific LBP. It is reported in the literature that EQ-5D-3L may not be sensitive enough to elicit the impact of interventions on pain (Garratt AM 2021, Wahlberg M 2021). Hence, using these generic health measures may underestimate the potential health impact associated with digital technologies. This means the results could be a more conservative estimation of the true impact of digital technologies for non-specific LBP.

The cost of the technologies ranged between companies, with the lowest identified cost of **management** and the highest identified cost of **management** application, whereas the highest cost is an application which can be used for non-specific LBP, offering physiotherapy, digital sessions with clinicians and other services. Therefore, despite the cost differences, these digital technologies are expected to have different effectiveness. However, based on the available evidence, it is not possible to capture each technology individually.

Long-term impacts

Due to the limited available evidence and the potential recurrence of non-specific LBP, a 1-year time horizon was used in the model. Hence, some potential longer-term benefits may be omitted from the analysis. For instance, if the use of these technologies supports a significant reduction in reported pain for people with chronic LBP, this may continue beyond 1 year, through the person having learned selfmanagement techniques for their own LBP. These benefits may be realised through quality-of-life improvements, or healthcare resource use reduction which occurs after 1 year. Currently, there is very limited evidence on the long-term impact of these technologies, so any potential benefit is uncertain. Another potential benefit which may impact long-term outcomes is the potential that the digital technologies which can be used on acute pain, may result in less people ending up with chronic non-specific LBP. This may be because the technologies reduce waiting times, so people can engage with self-management strategies sooner than standard care. If the technologies can support people at an earlier stage with their pain, the source of the issue may be resolved quicker than treating someone who has developed chronic LBP. Hinge Health provided some evidence that their technology has helped reduce people developing chronic pain compared with standard care, although this was a study conducted in the US, which may not be generalisable to the UK.

Hence, it may be the case that the current modelling approach is a conservative estimate of the impact of digital technologies for non-specific LBP. A longer time horizon could improve the cost-effectiveness of the digital technologies, assuming there are no further costs associated with implementation.

ACT for PAIN and its potential impact

As stated in section 8.2, it is likely that the cost-utility model is not representative for the potential impact of ACT for PAIN, as this is solely a psychological intervention and so is likely to use different resource use compared to the studies used to populate the early economic model. ACT for PAIN is not included in the model in any capacity, even the cost of the technology itself. ACT for PAIN has not submitted any evidence which supports the use of their technology, only ACT itself. No studies using ACT for PAIN were reported as part of the clinical or economic evidence reviews.

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 CBT. ACT for PAIN is expected to cost **mean** per person, which includes the lifetime cost and maintenance fee of enrolling someone into treatment. Limited evidence in the UK exists regarding the costs of ACT in the UK. However, as a proxy for the average cost of ACT, clinical feedback suggested CBT costs would be similar to ACT costs, although noted that ACT may cost more, given it is a more intensive treatment. Based on £81.74 per

CBT session from PSSRU for computerised CBT costs, and 7.5 as the average number of sessions (NHS 2021), the proxy cost for ACT would be £612.98 per person. Hence, at a cost of **or** per person, ACT for PAIN is approximately **or contract or be** than the estimated proxy, or for an episode of CBT treatment. The access to the treatment using ACT for PAIN would last a lifetime, which is not necessarily the case for digital forms of CBT. Hence, ACT for PAIN has the potential to cover costs of recurrence, however, how common this will be is unknown.

The current clinical and economic evidence base for ACT in the UK is also limited for the treatment of chronic pain (which includes non-specific LBP). This is summarised in NICE guidelines which included 2 clinical papers and 1 economic study (National Institute for Health and Care Excellence 2020a) as part of this guideline development. Within this guideline, 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. A more recent systematic review and meta-analysis included 33 RCTs, many of these studies being small and underpowered, (5 based in the UK) for ACT across a range of countries and suggested (Lai L 2023) ACT:

- Improved pain intensity and psychological outcomes compared with Standard care.
- Had a larger impact on physical function than pain intensity reported by individuals.
- 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.

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 (the difference in cost between ACT for PAIN and an episode of CBT treatment) in other healthcare costs, such as reducing primary care and secondary care visits, medications, and physiotherapy. In order to be cost-effective at a £20,000 per QALY threshold, ACT for PAIN is likely to require improvement to quality of life, and/or reduction in healthcare costs when compared to

other CBT or other forms of ACT. The estimated benefit required to be cost-effective 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.

This analysis is a crude estimation and a type of 'what if' analysis to determine the benefit ACT for PAIN would need to give in order to be cost-effective. A more comprehensive analysis should be conducted once more information and evidence becomes available. Given current evidence suggests that digital ACT may be less effective, the impact of ACT for PAIN is uncertain. Equally, given the limited economic evidence of ACT and its application in the UK, it is likely further evaluation should be considered on ACT more widely, given it is currently recommended as part of NICE guidelines for the management of chronic pain (National Institute for Health and Care Excellence 2020a).

9 Interpretation of the evidence

9.1 Interpretation of the clinical and economic evidence

In the context of the early value assessment, there is some evidence that suggests that 4 of the scope digital technologies used alongside standard care may result in a greater improvement of pain and physical function than standard care alone in people with non-specific LBP. However, studies reported outcomes across a range of different measures making it difficult to draw any certain conclusions across the data. Further, only short-term evidence was available as outcomes were most often reported at 12 weeks, with only one case series reporting pain scores beyond this timepoint at 24 weeks (Clement et al. 2018). Only 4 studies included a UK population. Therefore, clinical interpretation will be important to understand the usefulness and generalisability

of this evidence to the UK NHS setting. The studies identified indicated that digital technologies for non-specific LBP were plausibly safe with low rates of AEs, even though there was limited evidence to judge clinical effectiveness.

The EAG identified 16 relevant studies, of which 12 were prioritised for extraction and narrative synthesis because they were most clearly relevant to the scope. 5 RCTs compared digital technologies to standard care.

Of the 5 RCTs, 2 were powered to test differences in effect size between treatment groups in their reported outcome measures (Priebe et al. 2020a, Shebib et al. 2019). 1 reported that the Kaia app plus usual care resulted in a significantly greater percentage reduction of NRS 0-10 pain score compared to usual care alone at 12 weeks (Priebe et al. 2020a), and 1 reported greater reduction in MvK and VAS disability and pain scores (Shebib et al. 2019). 2 trials were powered to detect differences in outcomes scores at follow-up (Sandal et al. 2021, Toelle et al. 2019), 1 of which reported that selfBACK plus usual care resulted in significantly lower pain and disability scores compared to usual care at 12 weeks (Sandal et al. 2021). The other reported that the Kaia app resulted in significantly lower pain scores compared to physiotherapy at 12 weeks (Toelle et al. 2019). The only RCT conducted in the UK was a feasibility trial assessing SupportBack, which had a small sample size (n=87 patients) and was not powered to detect significant differences in effectiveness. The RCT found that SupportBack plus usual care and physiotherapist consultations resulted in larger reductions in NRS pain scores and NRS index than SupportBack plus usual care (Geraghty et al. 2018).

The remaining 7 studies were non-comparative studies of which 1 included a UK population and 3 included partial UK populations. Of these, 3 retrospective case series reported positive trends in pain outcomes and 1 reported positive trends in physical function outcomes that were not tested for significance. 1 retrospective case series reported positive patient and clinician satisfaction findings.

The EAG considers that, although this evidence provides uncertain indications of the comparative performance of digital technologies for non-specific LBP in the UK NHS

setting, it does suggest that it is plausible for digital technologies to have a positive clinical impact.

Evidence specific to acute and chronic LBP subgroups was limited and the reporting of these populations was poor in the literature: 1 RCT included people with acute LBP and 3 studies, including 1 RCT, included people with chronic LBP. Nevertheless, the evidence supported that it is plausible for digital technologies to have a positive clinical impact.

Reported adherence rates may overestimate the number of people able to use the technology in a real-world setting because access to a smartphone or tablet and the ability to speak the respective national language of each trial was a selection criterion in most of the studies.

The EAG identified the following concerns regarding the generalisability of findings:

- Versions: Different digital technologies have different features, making comparison difficult. Features that are consistent between the 5 technologies evaluated in the 12 prioritised studies include tailoring of content based on symptom tracking, exercise plans, educational content and mindfulness or CBT content. Some features unique to a particular technology include sensor-guidance for exercises to improve accuracy of home physiotherapy (Hinge) and AI-powered case-based reasoning methodology to improve tailoring of content to each user (Kaia app). Further, different iterations of the same app contain different features. For example, during 2017 the Kaia app was developed considerably to allow more customisation and more sensitive gradations of exercise difficulty (Clement et al. 2018). Comparing different technologies and their effectiveness is therefore difficult.
- **Population**: All 12 prioritised studies included people with non-specific back pain or people with LBP without spinal pathology or red flag signs and symptoms. However, limited information was available for the scoped subgroups of acute and chronic pain patients. 1 RCT (Priebe et al. 2020a) included people with acute LBP and 3 studies included people with chronic LBP: 1 RCT (Shebib et al. 2019), 1 prospective case series (Nordstoga et al. 2020) and 1 retrospective case series (Bailey et al. 2020). The remaining studies included mixed populations with respect to acute or chronic LBP, one of which reported pain outcomes for a subgroup of people with chronic pain (Toelle et al. 2019).

Clinical validation will be useful on the generalisability of this evidence applied to this specific population.

- **Comparator**: 4 of the 5 RCTs compared a digital technology plus standard care to standard care alone. These studies did not report the health care used as part of standard care in either arm. It is possible that used of digital technology has an interaction with standard care. For example, people receiving educational content and notifications through the app may be more aware of and likely to pursue standard care treatment than those in standard care arms alone. Without clear reporting on concomitant treatment in the intervention and control arms, this is a possible source of bias in patient-reported clinical outcome results.
- **UK NHS setting**: Of the 12 included and prioritised studies, 1 RCT (Geraghty et al. 2018) was conducted in a UK population, 1 prospective case series (Nordstoga et al. 2020) included a UK patient cohort, 1 retrospective case series included a UK patient cohort (Wanless and McClellan 2019) and 1 retrospective case series included international app use data in which an unreported number of participants were based in the UK (Clement et al. 2018).

4 technologies were evaluated in 5 RCTs. However, a wide range of outcome measures were reported across trials. Therefore, it is not possible to determine whether the evidence is generalisable between different technologies.

3 economic evaluations were identified, although none were specific to the UK population. From a healthcare perspective, there was mixed evidence regarding the cost-effectiveness of digital technologies for non-specific LBP. However, the evidence demonstrated the potential to be cost-effective when considering a wider societal perspective. 7 costing studies were also summarised in the evidence, which highlighted the potential that digital technologies could reduce healthcare resource use, and therefore healthcare costs. These studies were subject to biases, such as lack of peer review, mixed populations beyond just non-specific LBP and small sample sizes.

9.2 Integration into the NHS

Of the 4 digital health technology providers included within the scope of this evaluation and who submitted evidence, 3 of these are currently used within the NHS, as outlined in section 2.1. ACT for PAIN is currently used in the NHS, but does not have regulatory approval, such as CE or UCKA marking, or DTAC accreditation. If ACT for PAIN continues to be used in the NHS going forward, further clarification should be sought from the MHRA regarding whether the technology requires these accreditations. Where companies have submitted evidence, the digital technologies are noted to operate across a range of other MSK conditions, beyond non-specific LBP.

Clinical risk and safety netting for specific conditions

A risk associated with digital technologies is that some people using these applications may have a specific cause for their LBP but are being treated as if the LBP is nonspecific. The risk of this happening is likely determined by:

- If the digital technology includes a safety net feature upon engaging with the application, which asks questions designed to highlight specific conditions.
- Where the technology is placed in the care pathway.

For those who are being treated for chronic pain (such as using Pathway through Pain or ACT for PAIN), the lack of a safety net may be less of a concern, as people are likely to have been investigated over time to find the cause of the pain. Therefore, if there is an underlying medical concern, this is more likely to have been spotted prior. However, for technologies that can be used immediately from self-referral for acute pain, the risk of an underlying medical concern going unnoticed may be higher without an appropriate safety net. Safety net features are therefore likely to mitigate some of the risk of missed medical concerns for applications that can be accessed via self-referral.

Those with safety net features are listed in Table 2.1. Both getUBetter Ltd and Hinge Health outlined safety net features to prevent specific conditions being missed through the use of their technologies, which both could be used to treat acute pain. ACT for PAIN and Pathway through Pain do not provide safety features, although these apps are used only for those with chronic pain. For companies who have not submitted evidence, it is unclear if these safety net features exist on these technologies.

Clinical risk and suitable referrals

Key criteria that should be considered when determining if a person should receive support through one of the digital technologies include:

• Cognitive impairment, learning disabilities or problems with manual dexterity.

- Severe depression or anxiety, where there may be a risk of suicide.
- Accessibility issues, such as visual impairment, the inability to understand health-related information, or language barriers.
- Co-morbidities which may impact a person's ability to engage with the technology.
- Other issues which may impact the ability for a person to engage with the technology, such as the capability of the individual to use technology.

Further details of the above listed issues and other issues are detailed in the NICE scope (NICE 2022).

Those who are referred to the digital technologies should undergo screening by a healthcare professional for their suitability before referral, which should mitigate this risk. However, for those who can self-refer, there is a risk that some people may not actually be suitable. Pain Medicine Specialist Ltd, getUBetter Ltd and Hinge Health indicated that their technology can be accessed by self-referral. Hinge allows people to access to 1-to-1 digital appointments with clinicians, which could be used to clarify suitability for the application based on the initial information entered. getUBetter has an initial questionnaire. However, the sensitivity of the questionnaire in identifying the various clinical risks is unknown. Continued development of the screening questionnaires in the applications to identify criteria for those who are unsuitable is important, so that these people receive alternative care tailored to their needs.

The EAG recommends that the issues listed in the NICE scope, alongside those detailed in this section, are important considerations for implementing digital technologies.

Training & resource use considerations

Healthcare providers are expected to undertake some training to enable the delivery of the different digital technologies. This includes training on what the technology does, how it can support patient care, when it is suitable to refer to the application and how the technology works, in case they need to explain the application during the referral process. Only brief details have been provided on the training requirements across

company evidence, although all have stated the time required to train staff would be low.

Other resource use considerations include the pricing structures of the different technologies. Some technologies cost on a per person basis from referrals (or self-referrals) to the technology.

up-front charges should be considered as part of budgeting at a local level.

Potential impact on the current care pathway

Based on the evidence collected and clinical input, it is expected that these digital technologies are unlikely to significantly change the current care pathway. It is likely that these technologies will be used alongside standard care to support treatment for non-specific LBP, rather than cause a restructure of the care pathway.

The technologies listed are likely to facilitate faster access to self-management resources and psychological therapies than current standard care. Waiting times are a known issue within the management of non-specific LBP and any associated psychological treatment, with an average wait time of around 9 weeks and many people waiting beyond the 18-week target for any referral for treatment (NHS 2019a, Igwesi-Chidobe C.N 2021, Fowler Davis S 2022). Getting faster access to treatments prior to any further referral is one of the key value propositions of the associated technologies, which may drive any potential benefit that is accrued. In the case where psychological intervention is appropriate, such as for chronic pain, faster access may lead to quicker optimal management of an individual's pain, as well as a reduction in the impact of anxiety or depression.

9.3 Ongoing studies

Studies identified through EAG searches

The EAG searches did not identify ongoing studies evaluating any of the 9 target technologies. 3 recently completed studies of relevance to the scope were identified, none of which reported results.

NCT04290078 was a US based 2-arm RCT comparing chronic LBP outcomes amongst the Kaia app intervention group to a control group receiving usual care. The estimated completion date was June 2021. However, the trial record was last updated in December 2020.

NCT04411108 was a pilot validation study in the US, completed in September 2021. Exercise execution amongst patients with chronic non-specific LBP using the Kaia app were compared to control group exercises using handout instructions.

ISRCTN14736486 was a UK based 3-arm RCT completed in January 2022 to assess the clinical and cost-effectiveness of SupportBack in LBP patients, with or without sciatica. Participants were randomised to receive usual care, usual care + SupportBack, or usual care + SupportBack + telephone physiotherapist support.

Studies identified through company submissions

Company submission documents listed 4 ongoing studies evaluating technologies by 3 companies (Wellmind Health, getUBetter Ltd and Hinge Health). NCT05821530 was a 3-arm RCT comparing a high-frequency impulse therapy (HFIT) device to a standard transcutaneous electrical nerve stimulator and a control group for treatment of chronic LBP and knee pain. Although all participants were engaged in the Hinge app, the study was not considered relevant as it was primarily evaluating the HFIT device. A summary of the 3 studies considered to be relevant or partly relevant to the scope is provided in

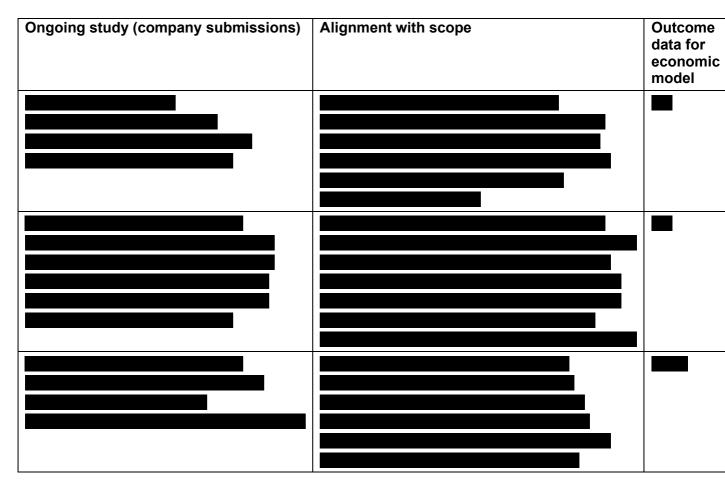
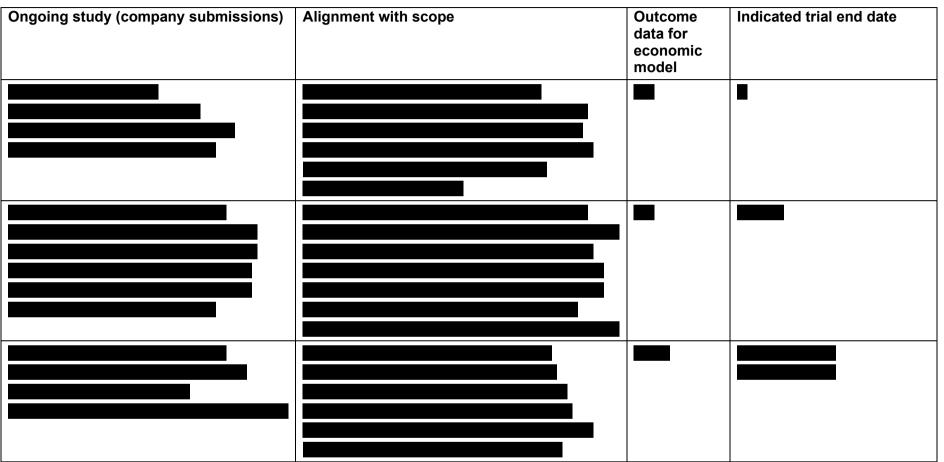


Table 9.1: Ongoing studies list from company submissions.

 Table 9.1: Ongoing studies list from company submissions



Key: HSDR – Health and social care delivery research, HQ – Health questionnaire, IPQ – Illness perception questionnaire, LBP – Low back pain, MSK – Musculoskeletal, NIHR – National institute for health and care research, NRS – Numerical rating scale, RCT – Randomised controlled trial, RMDQ – Roland-Morris disability questionnaire, TENS – Transcutaneous electronic nerve stimulator.

External assessment group report: Digital Technologies for Managing Low Back Pain Date: September 2023

10 Evidence gap analysis

Table 10.1: Clinical Evidence gap analysis

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|----------------------------------|-------------------|-------------------|---|---|-------------------|----------------------|-------------------|-----------------------------|-------------------|
| Intermediate outcom | es | | | | | | | | |
| Pain self-efficacy | No studies RED | No studies RED | 1 RCT powered to detect significant between- group differences at 3 and 9 months 1 prospective single-arm trial No UK evidence AMBER | 1 UK RCT, feasibility RCT with small sample sizes not powered to test for significance. | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Change in number appointments | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

External assessment group report: Digital Technologies for Managing Low Back Pain Date: September 2023

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|---|---|---|---|---|-------------------|----------------------|-------------------|-----------------------------|-------------------|
| Time to recovery (for acute LBP) | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Patient choice and preference | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Work productivity/Return to full activity | 1 retrospective case series, non-UK RED | 1 retrospective cohort study, non-UK RED | 1 prospective single-arm trial No UK evidence RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Intervention adherence and completion (number of exercise/therapy sessions completed, interaction with health professionals, education contents reviewed) | 1 retrospective case series, non-UK RED RED | 2 retrospective case series, partial UK population AMBER | 1 RCT powered to detect significant between- group differences at 3 and 9 months AMBER | 1 UK RCT, feasibility RCT with small sample sizes not powered to test for significance. | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|--|---|---|---|--|-------------------|----------------------|--|-----------------------------|-------------------|
| Engagement 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 | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Treatment satisfaction and engagement (patient opinion) | No studies RED | No studies RED | 1 RCT, non- UK 1 prospective case series, partial UK population 1 prospective single-arm trial, non-UK AMBER | No studies RED | No studies RED | No studies RED | 1 retrospective case series in a UK population RED | No studies RED | No studies RED |
| Intervention-related adverse effect | No studies RED | 1 RCT, non- UK 1 retrospective | 1 RCT, non- UK AMBER | 1 UK RCT, feasibility RCT with small sample sizes not powered to | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|----------------------------------|---|--|---|---|-------------------|----------------------|--|-----------------------------|-------------------|
| | | case series, international pop | | test for significance. | | | | | |
| | | AMBER | | AMBER | | | | | |
| Withdrawals/ discontinuations | 1 RCT, non- UK 1 retrospective case series non-UK AMBER | 2 RCTs, non- UK 1 retrosperctive 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 RCT, feasibility RCT with small sample sizes not powered to test for significance. | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Clinician satisfaction | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | 1 retrospective case series in a UK population RED | No studies RED | No studies RED |
| Clinical outcomes | | | | | | | | | |
| Physiotherapy referrals | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|--|-------------------|-------------------|-------------------|-------------------|-------------------|-----------------------------|-------------------|-----------------------------|-------------------|
| Treatment waiting list | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Self-removal from waiting list | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Reduced pharmacological management | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Reoccurrence of LBP | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Reduced imaging referrals | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Discharge rate | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|--|---|---|---|---|-------------------|-----------------------------|-------------------|-----------------------------|-------------------|
| Surgical referrals | Associated/ Proxy outcome, 1 RCT, non- UK 1 retrospective case series, non-UK RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Emergency department attendances | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| PROMs | | | | | | | | I | |
| Functional outcomes | 1 RCT powered to detect differences in effect size, non-UK AMBER | 2 RCTs, 1 powered to detect differences in effect size, 1 powered to find between- group differences in outcomes at 3 months, non-UK | 1 RCT powered to find between- group differences in outcomes at 3 months, non- UK 1 prospective single-arm trial | 1 UK RCT, feasibility RCT with small sample sizes not powered to test for significance. | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|----------|--|---|--|--|-------------------|----------------------|-------------------|-----------------------------|-------------------|
| | | AMBER | AMBER | | | | | | |
| Pain | 1 RCT powered to detect differences in effect size, non-UK 1 retrospective case series, non-UK AMBER | 2 RCTs, 1 powered to detect differences in effect size, 1 powered to find between- group differences in outcomes at 3 months non-UK 2 retrospective case series, partial UK population AMBER | 1 RCT powered to find between- group differences in outcomes at 3 months, non- UK 1 prospective single-arm trial AMBER | 1 UK RCT, feasibility RCT with small sample sizes not powered to test for significance. AMBER | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| HRQoL | 1 RCT powered to detect differences in effect size, non-UK | 1 RCT powered to find between- group differences in outcomes at 3 months, non-UK | 1 RCT powered to find between- group differences in outcomes at 3 months, non- UK | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

| Outcomes | Hinge | Kaia app | selfBACK | SupportBack | ACT for PAIN | Ascenti Reach* | getUBetter* | Pathway through Pain* | PhioEngage* |
|---|----------------------------|-------------------|--|-------------------|-------------------|----------------------|-------------------|-----------------------------|-------------------|
| | | AMBER | 1 prospective single-arm trial AMBER | | | | | | |
| Musculoskeletal health questionnaire | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Back specific disability score (Oswestry Disability Index for LBP) | 1 RCT, non- UK AMBER | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |
| Patient experience | No studies RED | No studies RED | 1 prospective case series RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED | No studies RED |

Key: HRQoL – Health-related quality of life; LBP – Low back pain, PROM – patient-reported outcome measure, RCT – Randomised Controlled Trial. *No studies met the scope

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

Table 10.2: Evidence gap analysis for key economic outcomes

| Outcomes | Gap in current evidence |
|---|---|
| Subgroups: Impact that different severities of pain scores have on the cost- effectiveness of digital technologies | Current studies capture some potential impact of digital technologies, but do not stratify to account for people's severity of pain at baseline. The difference in using digital technologies for non-specific LBP on resource use, costs, effectiveness and quality of life at different pain severities is currently unknown. Resource use data should also be collected and stratified for different severity of pain scores to populate an economic model. RED |
| Effectiveness evidence: Long-term outcomes | It is not clear if there any long-term impacts from using digital technologies for non-specific LBP, or if the benefits stop after use of the technology is discontinued. RED |
| Effectiveness evidence: Effect of variations in digital technology provisions for non- specific LBP | Many providers offer a range of services This includes features such as AI driven personalised content, tailored education to improve physiotherapy, CBT and other psychological support. There is little to assess the impact different functionality of digital technologies has on clinical or economic outcomes, and how this differs by acute or chronic pain. RED |
| Effectiveness evidence: Improvement in pain | Some evidence has been captured on improvement in pain with digital technologies. However, a range of metrics are used, meaning they are not comparable for economic evaluation, while the results are not broken down into different severities of pain. AMBER |
| Resource use: Impact of psychological treatment on resource use. | Although there was clinical evidence to demonstrate some potential impact of psychological interventions on pain (such as ACT and CBT), no study has captured differences in healthcare resource use from using applications than facilitate or provide psychological treatments. RED |
| Resource use: Impact of acute and chronic pain | Evidence is currently limited on how resource use differs between those with acute and chronic non-specific LBP. The model makes strong assumptions on the potential difference, such as assuming no difference between the subgroups, although further research should be conducted to understand this difference. RED |

| Outcomes | Gap in current evidence |
|--|---|
| Resource use: Wider healthcare resource use impact of digital technologies for self-management of non-specific LBP | No evidence relevant to the scope of this early value assessment was available to highlight the potential impact digital technologies which facilitate or provide self-management may have on healthcare resource use, such as medication use, or reduction in healthcare appointments. Data used in the economic model was from studies in wider MSK populations, including only early data, based on small sample size. Larger, more robust studies should be conducted in non-specific LBP. RED |
| Costs: Set up and training costs | Companies provide no evidence of the implementation or training resource use and costs to embed their technologies within the NHS. Further clarification should be sought on the required training, and if there are any wider implementation costs. The EAG notes for these types of intervention, this may only be small. AMBER |
| HRQoL Most appropriate measure of pain | Currently, clinical studies use a range of different pain scores to capture the potential impact a digital technology may have on pain. Clinical opinion should be sought on the most appropriate and robust pain score to collect in studies. This can be used to define health states in the future economic model. AMBER |
| HRQoL: Valuing HRQoL by pain scores | There is currently some evidence of the impact digital technologies may have on HRQoL, measured through EQ-5D and EQ-VAS. EQ-5D would be the most suitable generic measure to capture quality of life, although there are concerns it may not be sensitive enough for different types of pain in the literature (Garratt AM 2021, Wahlberg M 2021). Research should be conducted to value HRQoL for different pain severities, either using EQ-5D, or a vignette study. AMBER |

Key: ACT – Acceptance and Commitment therapy, CBT – Cognitive behavioural therapy, EAG – External assessment group, EQ-5D – EuroQol 5 dimension, EQ-VAS - EuroQol visual analogue scale, HRQoL – Health-related quality of life, LBP – Low back pain.

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

10.1 Summary and conclusions of evidence gap analysis

Clinical evidence meeting the scope was available for 5 of the 8 scoped technologies. Limited clinical evidence was available for getUBetter as only one retrospective case series was confirmed to include only people with non-specific LBP. Depriortised evidence on the getUBetter application was included in the economic evidence due to the very limited available evidence on economic outcomes. This should be interpreted with caution. Similarly, 2 costing studies were included in the economic evidence for Pathway through Pain due to very limited available evidence, despite the results of these studies being based on anyone with chronic MSK pain. Other clinical studies were excluded during study selection due to unspecified populations. Therefore, it is possible that more technologies would have been evaluated if populations were better reported in the evidence base. No clinical evidence relevant to the scope was identified for Ascenti Reach (Ascenti), ACT for PAIN (Pain Medicine Specialist Ltd), getUBetter (getUbetter Ltd) or Pathway through Pain (Wellmind Health). No clinical evidence was identified for PhioEngage (EQL Ltd), a technology identified by NICE shortly after publication of the final scope.

Although comparative evidence was identified for a number of key outcomes, including pain and functional outcomes, a range of outcome measures were used across the trials, thus making comparison across digital technologies difficult. The use of common outcome measures for key outcomes would facilitate the comparison of different technologies. Systematic collection of AE data should also be considered.

Other outcomes were not well-reported, including work productivity and patient experience and satisfaction. The evidence base was particularly scarce for the effect of digital technologies on referral rates for other services such as imaging, physiotherapy or surgical referrals and emergency department attendances.

There was insufficient evidence to consider whether the variation in components used across digital technologies, such as sensor-guided exercise and AI-powered guidancetailoring, impacted on outcomes.

10.2 Key areas for evidence generation

Suggestions for future evidence generation are summarised in Table 10.3. Evidence generation should focus on increasing certainty in the greater use of common outcome measures in the evidence base, which would facilitate comparison of different technologies.

Greater reporting of patient characteristics, particularly of the type of back pain, the number of people with acute or chronic LBP, and pain severity at baseline would expand the evidence base.

Further to this, healthcare resource use associated with different types of digital technologies should be collected to observe whether digital technologies could significantly reduce resource use. Studies should compare digital technologies with standard care compared with standard care alone over at least a one year follow up period and be conducted in a UK NHS setting.

Evidence generation should also focus on understanding the impact that the referral setting (such as referred or self-referred) and the placement of the digital technologies in the clinical pathway has on the effectiveness of the digital technologies. Furthermore, evidence around the relationship between acute LBP and the number of people who progress to chronic LBP should be gathered, through monitoring people's pain scores over time. Suggestions of how pain scores could be captured over time are detailed throughout section 10.

To address possible bias that may result from an interaction between digital technologies and standard care in trials comparing both to standard care alone, future trials or cohort studies could report data on concomitant treatment in digital technology experimental arms and the detail of standard care use in control arms. Such information may be forthcoming in 12-month results from the Rise-uP trial, the 3-month results of which were included in this review (Priebe et al. 2020a). The authors reported that the content of control group care will be clarified when routine data from the health insurances are merged with the primary data at the trial conclusion, so this information may be published alongside the final results.

Table 10.3: Evidence generation recommendations

| Research question | Recommended study design | Outcomes |
|--|--|---|
| Which components of DHTs are likely to drive differences in relevant outcomes | Qualitative studies investigating clinical perspectives on which are the most resource saving features of DHT. | Components of DHT to interrogate further |
| Patient uptake of digital technologies and | Mixed methods studies assessing patient adherence to DHT using | Patient adherence |
| facilitators of adherence | different solutions to maximise uptake and adherence. | Categorisation of solutions for digital exclusion and acceptability |
| | Conducted in the UK. | Facilitators and barriers of uptake |
| Understanding which pain score is most clinically useful and how pain scores relate to quality of life | With clinical input, deciding which pain score is most appropriate to collect in any study conducted. | HRQoL, provided for different severities of pain score. |
| | Then either a research study to map different pain scores (for example, mild, moderate and severe) onto indirect utility instruments such as EQ-5D-3L. | |
| | If this is not judged as feasible, a vignette study could be conducted to understand the relation of pain to HRQoL. | |
| Healthcare resource use associated with | Cluster RCTs, prospective controlled cohort studies or cluster non- | Physiotherapy referrals |
| different types of digital technologies | RCTs, comparing digital technologies with standard care compared | CBT or ACT sessions |
| | with standard care alone over at least a one year follow up period. | Occupational therapist appointments |
| | This should be done for each different application, especially those | GP appointments |
| | with are facilitating or providing psychological treatment. | Primary care appointments |
| | | Secondary care appointments |
| | Conducted in the UK. | Emergency care attendance |
| | | Medication use |

| Research question | Recommended study design | Outcomes |
|---|--|-------------------|
| What is the cost-effectiveness of different | Detailed in section 10.3. | Quality of life |
| digital technologies when used alongside | | Resource use |
| standard care | | Cost |
| Understanding the impact that the referral | Cluster RCTs, prospective controlled cohort studies or cluster non- | Patient adherence |
| setting (such as referred or self-referred) and | RCTs, comparing digital technologies with standard care compared | Quality of life |
| the placement in the pathway has on the effectiveness and cost-effectiveness | with standard care alone over at least a one year follow up period. Referral setting must be clearly captured. | Resource use |
| | If power can be achieved, could be stratified within the same study as subgroups. | |
| Understanding how different baseline pain | Cluster RCTs, prospective controlled cohort studies or cluster non- | Patient adherence |
| scores impact the effectiveness and cost- | RCTs, comparing digital technologies with standard care compared | Quality of life |
| effectiveness of different digital technologies when used alongside standard care | with standard care alone over at least a one year follow up period. | Resource use |
| | Either multiple studies can be conducted, or ideally, one larger study that is powered to analyse by subgroups, such as stratification of pain severity. | |

Key: ACT – Acceptance and commitment therapy, CBT – Cognitive behavioral therapy, DHT – Digital health technology, EQ-5D-3L, HRQoL – Health-related quality of life, RCT – Randomised controlled trial

10.3 Potential future conceptual model

When evidence is collected to bridge current evidence gaps on digital health technologies for non-specific LBP, a future model design would provide a more robust evaluation of the technologies. The EAG recommends a type of cohort state transition model (for example, a Markov model) for a future evaluation. A patient simulation model is not likely to be required, unless there is substantial heterogeneity among characteristics of the population of interest, which would be expected to have a large impact on the results.

In any state transition model, the health states should be based around different severities of pain. For example, health states may include minimal pain or no pain, mild pain, moderate pain or severe pain. These states should be based around pain scores from questionnaires such as the Oswestry Disability Index, Back Pain Functional Scale or Roland-Morris Disability Questionnaire. The questionnaire used to define health states should be based on which questionnaire is the most clinically relevant and reflective of measuring LBP. The benefit of a state-driven model based on pain is that subgroup analysis could be conducted on different pain severities. Digital technologies for LBP may only be cost-effective in those with more severe pain before using the technology or may be more cost-effective in those with less severe pain. This stratification of pain and its impact on cost-effectiveness is currently unknown.

As stated in section 0, either a vignette study or indirect methods of utility elicitation using EQ-5D-3L should be used to elicit quality of life for these pain health states. Concerns are highlighted in the literature of using EQ-5D-3L due to a lack of sensitivity (Garratt AM 2021) (Wahlberg M 2021). The EQ-5D-5L appears to be more sensitive but concerns remain around the accuracy of the generic measure and its application for LBP. This measure is not currently recommended by NICE, although it can be mapped on to EQ-5D-3L. The EAG recommends that a vignette study would be the most appropriate to capture quality of life for the health-economic model.

Data from any clinical studies that recorded pain information could then be used to track people by their specific health states over time, calculating transition probabilities

based on the proportion of people in specific pain health states, including the probability of pain recurrence. The time horizon should then be expanded beyond 1 year, with results extrapolated from the trial, to estimate the evolution of people's pain score. A time horizon of beyond 5 years is not recommended, given the risk of relapse and repeat treatment associated with LBP. Scenario analysis on the time horizon should be conducted in any future evaluation.

Healthcare resource use should also be captured by stratification of pain scores. Future studies should look to stratify the healthcare resource use over the follow up period based on what pain score was recorded at each interval. This can then be used to estimate healthcare resource use for each pain severity. For example, if pain scores are captured every 3 months for a year, and the first pain score recorded is representative of severe pain, those first 3 months would be used to calculate any healthcare resource use for severe pain. Hence, it would be possible to estimate healthcare resource use is likely to include medication use, physiotherapy appointments, occupational therapy, other primary and secondary care appointments, and any emergency attendances.

This model structure would be suitable for both self-management technologies and technologies that facilitate and provide psychological therapy, providing the psychological therapy would be expected to impact pain scores. Previous literature indicates how psychological therapies may reduce pain (Lai L 2023), so using a model based around pain states would be flexible enough for different types of digital technologies. It is expected that different resource use is likely for those undergoing psychological therapy for their pain, but this can be factored into the model for these specific technologies and their respective future RCTs and potential real-world evidence.

Waiting times would not need to be included directly in the modelling approach. This is because those who wait longer for treatment with standard care may incur worse pain or use more healthcare resource use due to waiting. Therefore, this would already be reflected in the model, so to include waiting time is likely to double count the potential

impact of the digital technologies. Waiting times are an important clinical consideration that should be factored into any future evaluation, even if not explicitly incorporated into the economic model.

11 Conclusions

11.1 Conclusions from the clinical evidence

Evidence was not available for 4 of the 9 scoped technologies. Comparative evidence was identified to indicate that digital technologies may be effective as adjunct treatments to standard care in improving pain and physical function outcomes compared to standard care alone. However, we note that range of outcome measures were used across the trials, making comparison across digital technologies difficult. The elements that comprise standard care were not well-reported in the intervention and control arms of these trials, introducing uncertainty. Evidence for other scoped outcomes, such as the effect on use of other healthcare resources, waiting time and work productivity, was limited.

Limited evidence was available on digital technologies in acute and chronic pain populations specifically as most comparative studies included patients of any LBP duration. No studies specifically assessed digital technologies in a self-referral setting as studies did not clearly report details on whether participants recruited outside primary care channels had a history of seeking primary care. Only 4 studies included UK populations and therefore clinical interpretation is required to determine how generalisable the findings are to a UK NHS context.

11.2 Conclusions from the economic evidence

Previous economic evidence

A total of 2 cost-effectiveness studies and 7 costing studies were identified. The 2 costeffectiveness studies were specific to the population outlined in section 1, focusing more on chronic pain. Neither of these cost-effectiveness evaluations were specific to the UK. The evaluations highlighted uncertainty regarding the cost-effectiveness of digital technologies for non-specific LBP from a healthcare perspective but demonstrated the potential for wider societal benefits from using these technologies. Of the 7 costing studies, none were fully aligned with the scope of this evaluation. However, these studies reported data on how digital technologies for the management of pain (not just non-specific LBP) may save healthcare resource use. Data from one of these studies was used as part of the EAG modelling due to the limited data resource use data for non-specific LBP.

Base case economic model results

The economic analyses conducted by the EAG was a cost-utility model to indicate the potential benefit of digital technologies for non-specific LBP. The analysis suggests that the incorporation of digital technologies into the NHS for non-specific LBP has the potential to be cost-effective and cost-saving based on the limited evidence available. The base case results of the analysis suggest that there is a potential cost saving of £84 per person and increase in QALYs of 0.01 when using digital technologies, compared with standard care. The EAG results differ to previous economic evaluation results due to the different healthcare perspective, the focus on a mixed population rather than just people with chronic LBP, the cost of the technologies incorporated into the evaluation, and the underlying resource use data available from a UK perspective.

However, the results are based on naive and limited data with a high level of uncertainty. Key areas of uncertainty are the expected impact on healthcare resource use from the digital technologies, the true HRQoL impact associated with digital technologies (which may be under captured with EQ-5D), long-term outcomes of using the digital technologies and the impact of safety netting features for specific conditions, particularly in technologies where people can self-refer. Model inputs were primarily sourced though clinical elicitation and company provided detail. Due to limited evidence, studies with a different population than the scoped population of this early value assessment were used to populate the model.

Key drivers of the model results

The sensitivity analysis indicated the likely key drivers of the economic results were:

- 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.
- Physiotherapy referrals and the number of appointments after being referred.

Future conceptual model

Limited evidence was available to model the potential impact of digital technologies for non-specific LBP. A future model could be developed to support decision-makers with:

- Capturing subgroups for different severities of pain.
- Understanding the potential impact on HRQoL over time when using digital technologies, particularly in the long-term.
- Providing a greater understanding of the impact of digital technologies that provide or facilitate psychological therapies, such as ACT or CBT.

11.3 Conclusions on the gap analysis

The primary evidence gap is a lack of comparable evidence from a UK NHS setting to compare the digital technologies with each other or with standard care across different referral settings (self-referred or referred from primary care). There is also limited evidence to identify differences in subgroups according to acute and chronic LBP, or to stratify by different severities of pain prior to beginning care.

The EAG identified several ideas for further evidence generation but consider the priority to be cluster randomised trials at practice level or prospective comparative studies producing evidence of patient safety and cost effectiveness in different referral settings. Differences in healthcare resource use is particularly important to collect in any future studies, given the lack of resource use data currently available. This

evidence is also particularly sparse for psychological interventions, such as CBT or ACT.

In summary, this EAG concludes that there is currently some existing evidence to suggest that these technologies may have a positive impact on health outcomes when used alongside Standard care. No evidence was identified that suggested the addition of digital technologies reduces patient safety. There was limited evidence on the impact digital technologies may have on healthcare resource use. Future evidence generation, particularly for an economic evaluation, would need to include the evaluation of long-term outcomes, determine if EQ-5D-3L is suitable for evaluating quality of life differences, understand the resource use implications, and stratify data collection by severities of pain.

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13 Appendices

Appendix A – Search methods

A MEDLINE (OvidSP) search strategy designed to identify studies of digital technologies for managing low back pain is presented below.

The main structure of the strategy comprises 2 concepts:

- Low back pain (search lines 1 to 5)
- Digital technologies (search lines 6 to 31).

The concepts are combined as follows: low back pain AND digital technologies.

In addition to the above approach, the strategy included a supplementary search strand designed to identify:

- Records referring to named technology providers/platforms included in the scope of this EVA (search lines 32 to 40).
- Records that refer to low back pain AND Kaia (search lines 41 to 42)

The strategy was devised using a combination of subject indexing terms and free text search terms in the Title, Abstract and Keyword Heading Word fields. The search terms were identified through discussion within the research team, scanning background literature and browsing database thesauri. Searches were not restricted by study design or outcome so were appropriate to retrieve both clinical and economic evidence.

The search terms for the digital technologies concept include the NICE search filter for health apps (Ayiku 2021) (search lines 6 to 20). To enhance sensitivity, this filter was expanded by adding searches of the keyword heading word field to all the natural language search lines. Further terms for digital technologies were added to the search strategy (search lines 21 to 30).

The strategy excluded animal studies from MEDLINE using a standard algorithm (search line 45). 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 lines 46).

Reflecting the eligibility criteria, the strategy was restricted to studies published in English (search line 49). 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 reporting studies of relevant technologies in broader MSK populations which do not have any terms for LBP in the database record would not be retrieved.

Before running the search the performance was tested using records for included studies from 2 systematic reviews ((Hewitt S 2020),(Moreno-Ligero M 2023)). The search retrieved all the included studies. This test suggested that the strategy was reasonably robust, although it is not possible to know how representative this test set is of all studies that were eligible for this review.

The approach taken in the search strategy is designed to strike an appropriate balance of sensitivity and precision.

Resources searched

We conducted the literature search in the databases and information resources shown in Table 13.1.

| Resource | Interface / URL | |
|---|------------------------|--|
| Databases | | |
| MEDLINE(R) ALL | OvidSP | |
| Embase | OvidSP | |
| Cochrane Database of Systematic Reviews(CDSR) | Cochrane Library/Wiley | |

Table 13.1: Databases and information sources searched

| 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 as well as retrieved relevant systematic reviews published since 2019, for additional eligible studies.

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 between 18 July 2023 and 19 July 2023 and identified 5880 records (Table 13.2). Following deduplication, 3870 records were assessed for relevance.

| Resource | Number of records identified |
|--|------------------------------|
| Databases | |
| MEDLINE | 1277 |
| Embase | 2496 |
| Cochrane Database of Systematic Reviews (CDSR) | 23 |
| Cochrane Central Register of Controlled Trials (CENTRAL) | 906 |
| Conference Proceedings Citation Index - Science (CPCI-S) | 128 |
| NHS Economic Evaluation Database (NHS EED) | 7 |
| EconLit | 8 |
| Total records identified through database searching | 4845 |
| Trials Registers | |
| ClinicalTrials.gov. | 396 |
| WHO International Clinical Trials Registry Portal (ICTRP) | 639 |
| Total records identified through trials register searching | 1035 |
| Other sources | |
| Reference list checking | |
| Company evidence | 6 |
| Total additional records identified through other sources | 6 |
| Total number of records retrieved | 5881 |
| Total number of records after deduplication | 3870 |

Table 13.2: Literature search results

Search strategies

A.1: Source: MEDLINE ALL

Interface / URL: OvidSP

Database coverage dates: 1946 to 17 July 2023

Search date: 18 July 2023

Retrieved records: 1277

Search strategy:

- 1 back pain/ 18966
- 2 low back pain/ 26640
- 3 ((lumbar or lumbosacral or lumbo-sacral or back) adj5 (pain* or ache* or neuropath* or neuralgi*)).ti,ab,kf. 69923
- 4 (backache* or lumbago or backpain*).ti,ab,kf. 5390
- 5 or/1-4 85018
- 6 mobile applications/ 11508
- 7 exp internet/ 97598
- 8 exp cell phone/ 22401
- 9 exp computers, handheld/ 13049
- 10 medical informatics applications/ 2551
- 11 therapy, computer-assisted/ 6973
- 12 (app or apps).ti,ab,kf. 44073
- 13 (online or web or internet or digital*).ti,kf.166452

- 14 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab.78848
- 15 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti,kf. 34096
- 16 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3
 (based or application* or intervention* or program* or therap*)).ab. 16838
- 17 (mobile health or mhealth or m-health or ehealth or e-health or emental or emental).ti,kf. 18885
- 18 ((mobile health or mhealth or m-health or ehealth or e-health or emental or emental) adj3 (based or application* or intervention* or program* or therap*)).ab. 5867
- 19 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab,kf.23060
- 20 or/6-19 368675
- 21 remote consultation/ 5738
- 22 telemedicine/37449
- 23 telenursing/ 251
- 24 telerehabilitation/ 994
- 25 ((remote* or virtual) adj3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)).ti,ab,kf. 23968
- 26 ((online or web or internet or digital*) adj3 (consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline*)).ti,ab,kf. 12645
- 27 (digital tech* or digital health*).ti,ab,kf. 13119

- 28 ((software or tech or technolog* or wearable*) adj3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)).ti,ab,kf. 96772
- 29 (telematic or tele-matic or telemanagement or tele-management or telenursing or teleservic* or tele-servic* or telemedic* or tele-nursing or teleservic* or tele-servic* or telemedic* or telehealth* or tele-health* or telecare or tele-care or tele-home or telehome or telecommunication* or tele-communication* or teleconferenc* or tele-conferenc* or tele-consult* or teleconsult* or tele-rehab* or telerehab* or teleconsult* or tele-consult* or telephysi* or teletherap* or tele-therap* or tele-physi* or telephysi* or telephysi* or teletherap* or tele-therap* or tele-physi* or telephysi* or telephysi*
- 30 virtual care.ti,ab,kf. 1252
- 31 or/20-30 519337
- 32 (pain medicine specialist or pain medicine specialistr or pain medicine specialisttm).ti,ab,kf,ot.
- 33 (Act for Pain* or act for pain or act for painr or act for paintm).ti,ab,kf,ot. 34
- 34 (ascenti or ascentir or ascentitm).ti,ab,kf,ot. 0
- 35 (getubetter* or get u better*).ti,ab,kf,ot. 1
- 36 hinge health*.ti,ab,kf,ot. 2
- 37 ("pathway through pain" or "pathway through paint" or "pathway through paintm" or wellmind or wellmindr or wellmindtm).ti,ab,kf,ot.
- 38 (selfback* or self back*).ti,ab,kf,ot. 22
- 39 (supportback* or support back or support backr or support backtm).ti,ab,kf,ot.22
- 40 or/32-39 97

- 41 kaia*.ti,ab,kf,ot. 298
- 42 5 and 31 1291
- 43 5 and 41 6
- 44 40 or 42 or 43 1371
- 45 exp animals/ not humans/ 5139017
- 46 (news or editorial or case reports).pt. or case report.ti. 3267757
- 47 or/45-46 8342198
- 48 44 not 47 1318
- 49 limit 48 to english language 1277

A.2: Source: EMBASE

Interface / URL: OvidSP

Database coverage dates: 1974 to 17 July 2023

Search date: 18 July 2023

Retrieved records: 2496

Search strategy:

- 1 backache/ 66176
- 2 low back pain/ 71561
- 3 ((lumbar or lumbosacral or lumbo-sacral or back) adj5 (pain* or ache* or neuropath* or neuralgi*)).ti,ab,kf,dq.
 102073
- 4 (backache* or lumbago or backpain*).ti,ab,kf,dq. 5454

5 or/1-4 161201

External assessment group report: Digital Technologies for Managing Low Back Pain Date: September 2023

- 6 exp mobile application/ 25089
- 7 internet/ 122876
- 8 exp mobile phone/ 46878
- 9 text messaging/ 7591
- 10 personal digital assistant/ 1821
- 11 computer assisted therapy/ 4857
- 12 (app or apps).ti,ab,kf,dq. 60019
- 13 (online or web or internet or digital*).ti,kf,dq. 197044
- 14 ((online or web or internet or digital*) adj3 (based or application* or intervention* or program* or therap*)).ab.105618
- 15 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).ti,kf,dq.39741
- 16 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) adj3
 (based or application* or intervention* or program* or therap*)).ab. 22434
- 17 (mobile health or mhealth or m-health or ehealth or e-health or emental or e-mental).ti,kf,dq.18398
- 18 ((mobile health or mhealth or m-health or ehealth or e-health or emental or emental) adj3 (based or application* or intervention* or program* or therap*)).ab. 6376
- 19 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).ti,ab,kf,dq. 27896
- 20 or/6-19 473150
- 21 exp telehealth/ 85544

- 22 ((remote* or virtual) adj3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)).ti,ab,kf,dq. 30494
- 23 ((online or web or internet or digital*) adj3 (consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline*)).ti,ab,kf,dq.
 17585
- 24 (digital tech* or digital health*).ti,ab,kf,dq. 13795
- 25 ((software or tech or technolog* or wearable*) adj3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)).ti,ab,kf,dq. 123170
- 26 (telematic or tele-matic or telemanagement or tele-management or telenursing or teleservic* or tele-servic* or telemedic* or tele-nursing or teleservic* or tele-servic* or tele-care or tele-home or telehome or telecommunication* or tele-communication* or teleconferenc* or tele-conferenc* or tele-consult* or teleconsult* or tele-rehab* or telerehab* or teleconsult* or tele-consult* or telephysi* or teletherap* or tele-therap* or tele-psyc* or telepsyc*).ti,ab,kf,dq. 59677
- 27 virtual care.ti,ab,kf,dq. 1513
- 28 or/20-27 678067
- (pain medicine specialist or pain medicine specialistr or pain medicine specialisttm).ti,ab,kf,dq,dv,my,ot,dm.
- 30 (Act for Pain* or act for pain or act for painr or act for paintm).ti,ab,kf,dq,dv,my,ot,dm. 59
- 31 (ascenti or ascentir or ascentitm).ti,ab,kf,dq,dv,my,ot,dm. 1
- 32 (getubetter* or get u better*).ti,ab,kf,dq,dv,my,ot,dm. 3

- 33 hinge health*.ti,ab,kf,dq,dv,my,ot,dm. 3
- 34 ("pathway through pain" or "pathway through painr" or "pathway through paintm" or wellmind or wellmindr or wellmindtm).ti,ab,kf,dq,dv,my,ot,dm.
- 35 (selfback* or self back*).ti,ab,kf,dq,dv,my,ot,dm. 22
- 36 (supportback* or support back or support backr or support backtm).ti,ab,kf,dq,dv,my,ot,dm. 28
- 37 or/29-36 142
- 38 kaia*.ti,ab,kf,dq,dv,my,ot,dm. 382
- 39 5 and 28 2547
- 40 5 and 38 6
- 41 37 or 39 or 40 2672
- 42 (animal/ or animal experiment/ or animal model/ or animal tissue/ or nonhuman/) not exp human/ 6769143
- 43 editorial.pt. or case report.ti. 1152294
- 44 preprint.pt. 77009
- 45 or/42-44 7951843
- 46 41 not 45 2594
- 47 limit 46 to english language 2496

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

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 7 of 12, July 2023

External assessment group report: Digital Technologies for Managing Low Back Pain Date: September 2023

Search date: 18 July 2023

Retrieved records: 23

Search strategy:

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

- #1 [mh ^"back pain"] 2872
- #2 [mh ^"low back pain"] 5850
- #3 ((lumbar or lumbosacral or "lumbo sacral" or back) near/5 (pain* or ache* or neuropath* or neuralgi*)):ti,ab,kw 19473
- #4 (backache* or lumbago or backpain*):ti,ab,kw 4806
- #5 #1 or #2 or #3 or #4 22164
- #6 [mh ^"mobile applications"]1568
- #7 [mh "internet"] 6180
- #8 [mh "cell phone"] 3129
- #9 [mh "computers, handheld"] 1369
- #10 [mh ^"medical informatics applications"] 38
- #11 [mh ^"therapy, computer-assisted"] 1477
- #12 (app or apps):ti,ab,kw 9399
- #13 (online or web or internet or digital*):ti,kw 22155
- #14 ((online or web or internet or digital*) near/3 (based or application* or intervention* or program* or therap*)):ab 19432

- #15 (phone* or telephone* or smartphone* or cellphone* or smartwatch*):ti,kw 15610
- #16 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) near/3(based or application* or intervention* or program* or therap*)):ab 9035
- #17 ("mobile health" or mhealth or "m health" or ehealth or "e health" or emental or "e mental"):ti,kw2504
- #18 (("mobile health" or mhealth or "m health" or ehealth or "e health" or emental or "e mental") near/3 (based or application* or intervention* or program* or therap*)):ab 2412
- #19 (mobile* near/3 (based or application* or intervention* or device* or technolog*)):ti,ab,kw8074
- #20 #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 59478
- #21 [mh ^"remote consultation"] 415
- #22 [mh ^"telemedicine"] 3557
- #23 [mh ^"telenursing"] 46
- #24 [mh ^"telerehabilitation"] 277
- #25 ((remote* or virtual) near/3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)):ti,ab,kw 5881
- #26 ((online or web or internet or digital*) near/3 (consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline*)):ti,ab,kw 4193
- #27 (digital next tech* or digital next health*):ti,ab,kw 1135

- #28 ((software or tech or technolog* or wearable*) near/3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)):ti,ab,kw 9136
- #29 (telematic or "tele matic" or telemanagement or "tele management" or telenursing or "tele nursing" or teleservic* or tele next servic* or telemedic* or tele next medic* or telehealth* or tele next health* or telecare or "tele care" or "tele home" or telehome or telecommunication* or tele next communication* or teleconferenc* or tele next conferenc* or tele next consult* or teleconsult* or tele next rehab* or telerehab* or teleconsult* or tele next consult* or tele next physi* or telephysi* or teletherap* or tele next therap* or tele next psyc* or telepsyc*):ti,ab,kw 11637
- #30 "virtual care":ti,ab,kw 85
- #31 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 76475
- #32 ("pain medicine specialist" or "pain medicine specialistr" or "pain medicine specialisttm"):ti,ab,kw
- #33 (Act for Pain* or "act for pain" or "act for painr" or "act for paintm"):ti,ab,kw 5
- #34 (ascenti or ascentir or ascentitm):ti,ab,kw 0
- #35 (getubetter* or "get u" next better*):ti,ab,kw 0
- #36 hinge next health*:ti,ab,kw 3
- #37 ("pathway through pain" or "pathway through paint" or "pathway through paintm" or wellmind or wellmindr or wellmindtm):ti,ab,kw
- #38 (selfback* or self next back*):ti,ab,kw 26
- #39 (supportback* or "support back" or "support backr" or "support backtm"):ti,ab,kw9

#40 kaia*:ti,ab,kw22

#41 #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 71

#42 #5 AND #31 826

#43 #41 OR #42 in Cochrane Reviews, Cochrane Protocols 23

A.4: Source: Cochrane Central Register of Controlled Trials (CENTRAL)

Interface / URL: Cochrane Library / Wiley

Database coverage dates: Information not found. Issue searched: Issue 7 of 12, July 2023

Search date: 18 July 2023

Retrieved records: 906

Search strategy:

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

#1 [mh ^"back pain"] 2872

#2 [mh ^"low back pain"] 5850

- #3 ((lumbar or lumbosacral or "lumbo sacral" or back) near/5 (pain* or ache* or neuropath* or neuralgi*)) 20528
- #4 (backache* or lumbago or backpain*) 4967
- #5 #1 or #2 or #3 or #4 23253
- #6 [mh ^"mobile applications"]1568
- #7 [mh "internet"] 6180

- #8 [mh "cell phone"] 3129
- #9 [mh "computers, handheld"] 1369
- #10 [mh ^"medical informatics applications"] 38
- #11 [mh ^"therapy, computer-assisted"] 1477
- #12 (app or apps)11843
- #13 (online or web or internet or digital*):ti,kw 22155
- #14 ((online or web or internet or digital*) near/3 (based or application* or intervention* or program* or therap*)) 24224
- #15 (phone* or telephone* or smartphone* or cellphone* or smartwatch*):ti,kw 15610
- #16 ((phone* or telephone* or smartphone* or cellphone* or smartwatch*) near/3(based or application* or intervention* or program* or therap*)) 11888
- #17 ("mobile health" or mhealth or "m health" or ehealth or "e health" or emental or "e mental"):ti,kw2504
- #18 (("mobile health" or mhealth or "m health" or ehealth or "e health" or emental or "e mental") near/3 (based or application* or intervention* or program* or therap*)) 4491
- #19 (mobile* near/3 (based or application* or intervention* or device* or technolog*))8435
- #20 #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR
 #16 OR #17 OR #18 OR #19 64133
- #21 [mh ^"remote consultation"] 415
- #22 [mh ^"telemedicine"] 3557
- #23 [mh ^"telenursing"] 46

- #24 [mh ^"telerehabilitation"] 277
- #25 ((remote* or virtual) near/3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*))
 6547
- #26 ((online or web or internet or digital*) near/3 (consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline*)) 5060
- #27 (digital next tech* or digital next health*) 1453
- #28 ((software or tech or technolog* or wearable*) near/3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*))
- #29 (telematic or "tele matic" or telemanagement or "tele management" or telenursing or "tele nursing" or teleservic* or tele next servic* or telemedic* or tele next medic* or telehealth* or tele next health* or telecare or "tele care" or "tele home" or telehome or telecommunication* or tele next communication* or teleconferenc* or tele next conferenc* or tele next consult* or teleconsult* or tele next rehab* or telerehab* or teleconsult* or tele next consult* or tele next physi* or telephysi* or teletherap* or tele next therap* or tele next psyc* or telepsyc*) 12272
- #30 "virtual care" 95
- #31 #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 85510
- #32 ("pain medicine specialist" or "pain medicine specialistr" or "pain medicine specialisttm")5
- #33 (Act for Pain* or "act for pain" or "act for painr" or "act for paintm") 6
- #34 (ascenti or ascentir or ascentitm) 3

#35 (getubetter* or "get u" next better*) 0

#36 hinge next health* 3

#37 ("pathway through pain" or "pathway through paint" or "pathway through paintm" or wellmind or wellmindr or wellmindtm) 1

#38 (selfback* or self next back*) 12

- #39 (supportback* or "support back" or "support backr" or "support backtm") 9
- #40 kaia* 40
- #41 #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 79
- #42 #5 AND #31 1380
- #43 #41 OR #42 in Trials 906

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

Interface / URL: Web of Science

Database coverage dates: 1990 to present

Search date: 18 July 2023

Retrieved records: 128

Search strategy:

Searches were conducted in the advanced search interface with the "exact search" option selected for all search lines.

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

1 TS=((lumbar OR lumbosacral OR lumbo-sacral OR back) NEAR/5 (pain* OR ache* OR neuropath* OR neuralgi*)) 3,999

- 2 TS=(backache* OR lumbago OR backpain*) 103
- 3 #2 OR #1 4,088
- 4 TS=(app OR apps) 18,447
- 5 TI=(online OR web OR internet OR digital*) 185,741
- 6 AK=(online OR web OR internet OR digital*) 139,213
- TS=((online OR web OR internet OR digital*) NEAR/3 (based OR application*
 OR intervention* OR program* OR therap*)) 107,908
- 8 TI=(phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)
 18,190
- 9 AK=(phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)
 11,037
- TS=((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)
 NEAR/3 (based OR application* OR intervention* OR program* OR therap*))
 11,859
- 11 TI=("mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)3,026
- 12 AK=("mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental)4,008
- TS=(("mobile health" OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) NEAR/3 (based OR application* OR intervention* OR program* OR therap*))
- 14 TS=(mobile* NEAR/3 (based OR application* OR intervention* OR device* OR technolog*)) 72,331

- 15 #14 OR #13 OR #12 OR #11 OR #10 OR #9 OR #8 OR #7 OR #6 OR #5 OR #4 399,803
- 16 TS=((remote* OR virtual) NEAR/3 (based OR application* OR intervention* OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*)) 41,858
- 17 TS=((online OR web OR internet OR digital*) NEAR/3 (consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline*)) 14,962
- 18 TS=("digital tech*" OR "digital health*") 5,476
- 19 TS=((software OR tech OR technolog* OR wearable*) NEAR/3 (based OR application* OR intervention* OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*)) 164,645
- 20 TS=(telematic OR tele-matic OR telemanagement OR tele-management OR telenursing OR tele-nursing OR teleservic* OR tele-servic* OR telemedic* OR tele-medic* OR telehealth* OR tele-health* OR telecare OR tele-care OR telehome OR telehome OR telecommunication* OR tele-communication* OR teleconferenc* OR tele-conferenc* OR tele-consult* OR teleconsult* OR tele-rehab* OR telerehab* OR teleconsult* OR tele-consult* OR tele-physi* OR telephysi* OR teletherap* OR tele-therap* OR tele-psyc* OR telepsyc*) 34,215
- 21 TS="virtual care" 38
- 22 #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 606,676
- 23 TS=("pain medicine specialist" OR "pain medicine specialistr" OR "pain medicine specialisttm")0

| 24 | TS=(Act for Pain* | OR "act for | pain" OR | "act for painr" | OR "act for | paintm") | 0 |
|----|-------------------|-------------|----------|-----------------|-------------|----------|---|
| | ` | | - | | | . / | |

- 25 TS=(ascenti OR ascentir OR ascentitm) 0
- 26 TS=(getubetter* OR "get u better*") 0
- 27 TS="hinge health*" 0
- 28 TS=("pathway through pain" OR "pathway through painr" OR "pathway through paintm" OR wellmind OR wellmindr OR wellmindtm) 0
- TS=(selfback OR "self back" OR selfbackr OR "self backr" OR selfbacktm OR
 "self backtm")
- 30 TS=(supportback* OR "support back" OR "support backr" OR "support backtm")
 15
- 31 TS=kaia* 28
- 32 #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 49
- 33 #3 AND #22 80
- 34 #32 OR #33 129
- 35 #32 OR #33 and English (Languages) 128

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: 18 July 2023

Retrieved records: 7

Search strategy:

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

| 1 | MeSH DESCRIPTOR back pain 146 |
|----|---|
| 2 | MeSH DESCRIPTOR low back pain 531 |
| 3 | ((lumbar OR lumbosacral OR lumbo-sacral OR back) NEAR5 (pain* OR ache* OR neuropath* OR neuralgi*)) 1005 |
| 4 | ((pain* OR ache* OR neuropath* OR neuralgi*) NEAR5 (lumbar OR lumbosacral OR lumbo-sacral OR back)) 298 |
| 5 | ((backache* OR lumbago OR backpain*)) 25 |
| 6 | #1 OR #2 OR #3 OR #4 OR #5 1030 |
| 7 | MeSH DESCRIPTOR mobile applications 5 |
| 8 | MeSH DESCRIPTOR Internet EXPLODE ALL TREES257 |
| 9 | MeSH DESCRIPTOR Cell Phone EXPLODE ALL TREES 36 |
| 10 | MeSH DESCRIPTOR Computers, Handheld EXPLODE ALL TREES 13 |
| 11 | MeSH DESCRIPTOR Medical Informatics Applications 8 |
| 12 | MeSH DESCRIPTOR therapy, computer-assisted 111 |
| 13 | (app OR apps) 133 |
| 14 | (online OR web OR internet OR digital*):TI 310 |
| 15 | ((online OR web OR internet OR digital*) NEAR3 (based OR application* OR intervention* OR program* OR therap*)) 350 |

- 16 ((based OR application* OR intervention* OR program* OR therap*) NEAR3
 (online OR web OR internet OR digital*))
 174
- 17 (phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*):TI165
- 18 ((phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*)
 NEAR3 (based OR application* OR intervention* OR program* OR therap*))
 198
- 19 ((based OR application* OR intervention* OR program* OR therap*) NEAR3
 (phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch*))
 154
- 20 (mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental):TI 29
- 21 ((mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental) NEAR3 (based OR application* OR intervention* OR program* OR therap*))
 19
- ((based OR application* OR intervention* OR program* OR therap*) NEAR3
 (mobile health OR mhealth OR m-health OR ehealth OR e-health OR emental
 OR e-mental))
 3
- 23 (mobile* AND (based OR application* OR intervention* OR device* OR technolog*)) 181
- 24 #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 1323
- 25 MeSH DESCRIPTOR remote consultation 89
- 26 MeSH DESCRIPTOR telemedicine 372
- 27 MeSH DESCRIPTOR telenursing 5

- 28 MeSH DESCRIPTOR Telerehabilitation 1
- 29 (((remote* OR virtual) AND (based OR application* OR intervention* OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*))) 406
- 30 ((online OR web OR internet OR digital*) NEAR3 (consult* OR treat* OR manag*
 OR advice OR advise* OR advising OR recommend* OR guidance OR
 guideline*)) 83
- 31 ((consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline*) NEAR3 (online OR web OR internet OR digital*)) 53
- 32 (digital tech* OR digital health*) 4
- 33 ((software OR tech OR technolog* OR wearable*) NEAR3 (based OR application* OR intervention* OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*))
- 34 ((based OR application* OR intervention* OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*) NEAR3 (software OR tech OR technolog* OR wearable*)) 697
- 35 ((telematic OR tele-matic OR telemanagement OR tele-management OR telenursing OR tele-nursing OR teleservic* OR tele-servic* OR telemedic* OR tele-medic* OR telehealth* OR tele-health* OR telecare OR tele-care OR telehome OR telehome OR telecommunication* OR tele-communication* OR teleconferenc* OR tele-conferenc* OR tele-consult* OR teleconsult* OR teleconsult* OR tele-rehab* OR telerehab* OR teleconsult* OR tele-consult* OR tele-physi* OR telephysi* OR teletherap* OR tele-therap* OR tele-psyc* OR telepsyc*)) 501

36 (virtual care) 0

- 37 #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 5281
- 38 (pain medicine specialist OR pain medicine specialistr OR pain medicine specialisttm) 0
- 39 (Act for Pain* OR act for pain OR act for painr OR act for paintm) 0
- 40 (ascenti OR ascentir OR ascentitm) 0
- 41 (getubetter* OR get u better*) 0
- 42 (hinge health*) 0
- 43 ("pathway through pain" OR "pathway through painr" OR "pathway through paintm" OR wellmind OR wellmindr OR wellmindtm) 0
- 44 (selfback* OR self back*) 0
- 45 (supportback* OR support back OR support backr OR support backtm) 0
- 46 (kaia*)0
- 47 #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 0
- 48 #6 AND #37 45
- 49 #47 OR #48 45
- 50 (#49) IN NHSEED 7

A.7: Source: Econlit

Interface / URL: OvidSP

Database coverage dates: 1886 to 6 July 2023

Search date: 18 July 2023

Retrieved records: 8

Search strategy:

Given the small numbers retrieved in this database it was decided to simplify the translation from MEDLINE to Econlit by removing the digital technologies concept.

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

- ((lumbar or lumbosacral or lumbo-sacral or back) adj5 (pain* or ache* or neuropath* or neuralgi*)).af.
 57
- 2 (backache* or lumbago or backpain*).af. 2
- 3 or/1-2 59
- 4 (app or apps).af. 593
- 5 (online or web or internet or digital*).af. 40116
- 6 (phone* or telephone* or smartphone* or cellphone* or smartwatch*).af. 4640
- 7 (mobile health or mhealth or m-health or ehealth or e-health or emental or emental).af. 125
- 8 (mobile* adj3 (based or application* or intervention* or device* or technolog*)).af.
 1004
- 9 or/4-8 44386
- 10 ((remote* or virtual) adj3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)).af. 313

- 11 ((software or tech or technolog* or wearable*) adj3 (based or application* or intervention* or consult* or treat* or manag* or advice or advise* or advising or recommend* or guidance or guideline* or therap* or program*)).af. 26919
- 12 (telematic or tele-matic or telemanagement or tele-management or telenursing or teleservic* or tele-servic* or telemedic* or tele-nursing or teleservic* or tele-servic* or tele-care or tele-home or telehome or telecommunication* or tele-communication* or teleconferenc* or tele-conferenc* or tele-consult* or teleconsult* or tele-rehab* or telerehab* or teleconsult* or tele-consult* or telephysi* or teleherap* or tele-therap* or tele-physi* or telephysi* or telephysi* or teletherap* or tele-therap* or tele-physi* or telephysi* or telephysi*
- 13 virtual care.af. 0
- 14 or/9-13 77977
- 15 (pain medicine specialist or pain medicine specialistr or pain medicine specialisttm).af.
- 16 (Act for Pain* or act for pain or act for painr or act for paintm).af. 0
- 17 (ascenti or ascentir or ascentitm).af. 0
- 18 (getubetter* or get u better*).af. 0
- 19 hinge health*.af. 0
- 20 ("pathway through pain" or "pathway through paint" or "pathway through paintm" or wellmind or wellmindr or wellmindtm).af.
- 21 (selfback* or self back*).af.2
- 22 (supportback* or support back or support backr or support backtm).af. 0
- 23 kaia*.af. 1
- 24 or/15-23 3

- 25 3 and 14 5
- 26 24 or 25 8
- 27 limit 26 to english 8

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: 19 July 2023

Retrieved records: 396

Search strategy:

The following 3 separate searches were conducted separately. All search terms were entered using the Expert interface:

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

The results from each search were downloaded as an individual set. The total number of records retrieved represents the sum of all searches, and includes duplicates caused by the same record being retrieved in each search.

Field searching was used for the first 2 searches below to ensure retrieved numbers remained manageable within the project context.

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

Search 1

AREA[ConditionSearch](((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)) AND AREA[InterventionSearch](app OR apps OR online OR web OR internet OR digital OR digitally OR phone OR phones OR telephone OR telephones OR smartphone OR smartphones OR cellphone OR cellphones OR smartwatch OR smartwatches OR mhealth OR m-health OR ehealth OR e-health OR emental OR e-mental OR mobile OR mobiles)

=214 studies

Search 2

AREA[ConditionSearch](((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)) AND AREA[InterventionSearch](remote OR remotes OR remotely OR virtual OR software OR tech OR technology OR technologies OR wearable OR wearables OR telematic OR tele-matic OR telematics OR tele-matics OR telemanagement OR tele-management OR telenursing OR tele-nursing OR teleservice OR teleservices OR tele-service OR tele-services OR telemedic OR telemedicine OR telemedicines OR telemedical OR tele-medic OR tele-medics OR telemedicine OR tele-medicines OR tele-medical OR telehealth OR telehealthcare OR telehealth OR tele-healthcare OR telecare OR tele-care OR tele-home OR telehome OR telecommunication OR telecommunications OR tele-communication OR telecommunications OR teleconference OR teleconferences OR teleconferencing OR teleconference OR tele-conferences OR tele-conferencing OR tele-consult OR teleconsults OR tele-consultation OR tele-consultations OR teleconsult OR teleconsults OR teleconsultation OR teleconsultations OR tele-rehab OR tele-rehabilitation OR telerehab OR telerehabilitation OR tele-physiotherapy OR tele-physiotherapist OR telephysiotherapists OR tele-physical OR tele-physio OR telephysiotherapy OR telephysiotherapist OR telephysiotherapists OR telephysical OR telephysio OR teletherapy OR teletherapies OR teletherapeutic OR teletherapeutics OR tele-therapy

OR tele-therapies OR tele-therapeutic OR tele-therapeutics OR tele-psychiatry OR telepsychiatric OR tele-psychiatrics OR tele-psychiatrist OR tele-psychiatrists OR telepsychology OR tele-psychologist OR tele-psychologists OR telepsychiatry OR telepsychiatric OR telepsychiatrics OR telepsychiatrist OR telepsyciatrists OR telepsychology OR telepsychologist OR telepsychologists)

= 165 studies

Search 3

("pain medicine specialist" OR "pain medicine specialistr" OR "pain medicine specialisttm" OR Act for Pain OR Act for Painr OR Act for Paintm OR "act for pain" OR "act for painr" OR "act for paintm" OR ascenti OR ascentir OR ascentitm OR getubetter OR getubetterr OR getubettertm OR "get u better" OR "get u better" OR "get u bettertm" OR "hinge health" OR "hinge healthr" OR "hinge healthtm" OR "pathway through pain" OR "pathway through painr" OR "pathway through paintm" OR wellmind OR wellmindr OR wellmindtm OR selfback OR selfbackr OR selfbacktm OR "self back" OR "self backr" OR "self backtm" OR "support backtm" OR kaia OR kaiar OR kaiatm)

=17 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 November 2022 and July 2023

Search date: 19 July 2023

Retrieved records: 639

Search strategy:

The following 5 searches were conducted separately using the search interface at the above URL. 'Without Synonyms' was selected for all searches.

The results from each search were downloaded as an individual set. The total number of records retrieved represents the sum of all searches, and includes duplicates caused by the same record being retrieved in each search.

Given the smaller numbers retrieved in this database it was decided not to combine terms for Kaia with LBP terms.

Search 1

(((lumbar OR lumbosacral OR lumbo-sacral OR back) AND (pain* OR ache* OR neuropath* OR neuralgi*)) OR (backache* OR lumbago OR backpain*)) AND (app OR apps OR online OR web OR internet OR digital* OR phone* OR telephone* OR smartphone* OR cellphone* OR smartwatch* OR mhealth OR m-health OR ehealth OR e-health OR emental OR mobile*)

=301 results

Search 2

(((lumbar OR lumbosacral OR lumbo-sacral OR back) AND (pain* OR ache* OR neuropath* OR neuralgi*)) OR (backache* OR lumbago OR backpain*)) AND ((remote* OR virtual) AND (based OR application* OR intervention* OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*))

=96 results

Search 3

(((lumbar OR lumbosacral OR lumbo-sacral OR back) AND (pain* OR ache* OR neuropath* OR neuralgi*)) OR (backache* OR lumbago OR backpain*)) AND ((software OR tech OR technolog* OR wearable*) AND (based OR application* OR intervention*

OR consult* OR treat* OR manag* OR advice OR advise* OR advising OR recommend* OR guidance OR guideline* OR therap* OR program*))

= 174 results

Search 4

(((lumbar OR lumbosacral OR lumbo-sacral OR back) AND (pain* OR ache* OR neuropath* OR neuralgi*)) OR (backache* OR lumbago OR backpain*)) AND (telematic OR tele-matic OR telemanagement OR tele-management OR telenursing OR telenursing OR teleservic* OR tele-servic* OR telemedic* OR tele-medic* OR telehealth* OR tele-health* OR telecare OR tele-care OR tele-home OR telehome OR telecommunication* OR tele-communication* OR teleconferenc* OR tele-conferenc* OR tele-consult* OR teleconsult* OR tele-rehab* OR telerehab* OR teleconsult* OR tele-consult* OR tele-physi* OR telephysi* OR teletherap* OR tele-therap* OR telepsyc* OR telepsyc* OR "virtual care")

= 43 results

Search 5

("pain medicine specialist" OR "pain medicine specialistr" OR "pain medicine specialisttm" OR Act for Pain* OR "act for pain" OR "act for painr" OR "act for paintm" OR ascenti OR ascentir OR ascentitm OR getubetter* OR "get u better*" OR "hinge health*" OR "pathway through pain" OR "pathway through painr" OR "pathway through paintm" OR wellmind OR wellmindr OR wellmindtm OR selfback* OR "self back*" OR supportback* OR "support back" OR "support backr" OR "support backtm" OR kaia*)

= 25 results

Appendix B – List of studies excluded at full text assessment (n=369)

Table13.3: List of excluded studies (N=369)

| Reference | Exclusion reason |
|--|---|
| Academy J. 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 NR separately |
| Achalandabaso A. New technologies in the management of lumbopelvic pain. Identifier: NCT04685837. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2020. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02233525/full. | Unnamed intervention |
| Achten JPJ, Mooren-van der Meer S, Pisters MF, Veenhof C, Koppenaal T, Kloek CJJ. Self-management behaviour after a physiotherapist guided blended self-management intervention in patients with chronic low back pain: a qualitative study. Musculoskeletal Science and Practice. 2022.62:102675. doi: <u>https://dx.doi.org/10.1016/j.msksp.2022.102675</u> | Eligible non-scoped intervention |
| Adeyinka A. Effect of telerehabilitation-based core-stability exercise on pain-related disability, pain self-efficacy and psychological factors in patients with non-specific chronic low back pain. Identifier: PACTR202208607830603. In: Pan African Clinical Trials Registry (PACTR) [internet]. Tygerberg: South African Cochrane Centre: 2022. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02458328/full. | Unnamed intervention |
| Agarwal A, Hogan T, Heapy A, LePage J, Makris U. Feasibility of assessing steps, pain and mood using the annie texting platform in older veterans with chronic back pain and depression. J Am Geriatr Soc. 2021.69(Suppl 1):S253. doi: <u>https://dx.doi.org/10.1111/jgs.17115</u> | Abstract - insufficient information |
| Ahlqwist A, Lundberg M, Brisby H, Varkey E, Kemani M. Get-Backyouth -development of a person-centered digital support platform for adolescents with low back pain who are seeking primary care. Pain Pract. 2022.22(Suppl 2):32. doi: <u>https://dx.doi.org/10.1111/papr.13128</u> | Not a primary study |
| Alduraywish R, Hendrick P, Blake H. Development and feasibility testing of web-based intervention for self-management of low back pain in nurses: a mixed-method study. Physiotherapy. 2021.113(Supp 1):e127-e28. doi: https://dx.doi.org/10.1016/j.physio.2021.10.115 | Abstract - insufficient info |
| Alegre HdCdP. Effects of an exercise program under supervision and unsupervised in the treatment of low back pain. Identifier: NCT02703402. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2016. Available from https://classic.clinicaltrials.gov/show/NCT02703402. | Intervention - not DHT for self-management or psychological support |

External assessment group report: Digital Technologies for Managing Low Back Pain Date: September 2023

| Reference | Exclusion reason |
|--|---|
| Almeida L, Costa LOP, Maher CG, Yamato TP, Fandim JV, Dear B, et al. Telerehabilitation for acute, subacute and chronic low back pain. Cochrane Database Syst Rev. 2020.2020(8):CD013704. doi: <u>https://dx.doi.org/10.1002/14651858.CD013704</u> | Ineligible SR |
| Almeria Ud. A study protocol comparing a home rehabilitation program versus e-health program in low back pain. Identifier: NCT04283370. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2020. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02082726/full. | CT record - no results |
| Almeria Ud. Effectiveness of a home rehabilitation program vs an e-health program in patients with chronic low back pain. Identifier: NCT03469024. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2018. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01567274/full. | Intervention - not DHT for self-man or psychological support |
| Almhdawi KA, Obeidat DS, Kanaan SF, Oteir AO, Mansour ZM, Alrabbaei H. Efficacy of an innovative smartphone application for office workers with chronic non-specific low back pain: a pilot randomized controlled trial. Clin Rehabil. 2020.34(10):1282-91. doi: <u>https://dx.doi.org/10.1177/0269215520937757</u> | Eligible non-scoped intervention |
| Alumni & Advancement Office LTU. The effect of physiotherapy integrated motivational interviewing and smartphone technology to increase physical activity in patients with low back pain: a cluster randomised controlled trial. Identifier: ACTRN12615000724572. 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-01796772/full. | Population - specific LBP |
| Alzahrani H, Mackey M, Stamatakis E, Shirley D. Wearables-based walking program in addition to usual physiotherapy care for the management of patients with low back pain at medium or high risk of chronicity: a pilot randomized controlled trial. PLoS ONE. 2021.16(8):e0256459. doi: <u>https://dx.doi.org/10.1371/journal.pone.0256459</u> | Intervention - not DHT for self-management or psychological support |
| Amorim AB, Pappas E, Simic M, Ferreira ML, Jennings M, Tiedemann A, et al. Integrating mobile-health, health coaching, and physical activity to reduce the burden of chronic low back pain trial (IMPACT): apilot randomised controlled trial. BMC Musculoskelet Disord. 2019.20(1):71. doi: https://dx.doi.org/10.1186/s12891-019-2454-y | Intervention - not DHT for self-management or psychological support |
| Amorim AB, Pappas E, Simic M, Ferreira ML, Tiedemann A, Jennings M, et al. Integrating mobile health and physical activity to reduce the burden of chronic low back pain trial (IMPACT): a pilot trial protocol. BMC Musculoskelet Disord. 2016.17(36)doi: <u>https://dx.doi.org/10.1186/s12891-015-0852-3</u> | Eligible non-scoped intervention |
| Anan T, Kajiki S, Oka H, Fujii T, Kawamata K, Mori K, et al. Effects of an artificial intelligence-assisted health program on workers with neck/shoulder pain/stiffness and low back pain: randomized controlled trial. JMIR Mhealth Uhealth. 2021.9(9):e27535. doi: <u>https://dx.doi.org/10.2196/27535</u> | Population - mixed and outcomes NR separately |

| Reference | Exclusion reason |
|---|---|
| Areias AC, Costa F, Janela D, Molinos M, Moulder RG, Lains J, et al. Impact on productivity impairment of a digital care program for chronic low back pain: a prospective longitudinal cohort study. Musculoskeletal Science and Practice. 2023.63:102709. doi: <u>https://dx.doi.org/10.1016/j.msksp.2022.102709</u> | Population - specific LBP |
| Australia M. 'TEXT4myBACK' text message intervention to improve pain and disability in people with low back pain. Identifier: ACTRN12618001263280. 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://www.cochranelibrary.com/central/doi/10.1002/central/CN-02445303/full. | CT record - no results |
| Axomove. Assessing the impact of the axomove therapy medical device on low back pain patients. Identifier: NCT05910463. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2023. Available from https://classic.clinicaltrials.gov/show/NCT05910463. | Eligible non-scoped intervention |
| Bach K, Szczepanski T, Aamodt A, Gundersen OE, Mork PJ. Case representation and similarity assessment in the SELFBACK decision support system. In: Case-Based Reasoning Research and Development; October 31 - November 2, 2016 2016: Atlanta, GA, US; 32-46. | Not a primary study |
| Barreveld AM, Rosen Klement ML, Cheung S, Axelsson U, Basem JI, Reddy AS, et al. An artificial intelligence-powered, patient-centric digital tool for self-management of chronic pain: a prospective, multicenter clinical trial. Pain Med. 2023.27:27. doi: <u>https://dx.doi.org/10.1093/pm/pnad049</u> | Population - mixed and outcomes NR separately |
| Baumeister H, Paganini S, Sander LB, Lin J, Schlicker S, Terhorst Y, et al. Effectiveness of a guided internet- and mobile- based intervention for patients with chronic back pain and depression (WARD-BP): a multicenter, pragmatic randomized controlled trial. Psychother Psychosom. 2021.90(4):255-68. doi: <u>https://dx.doi.org/10.1159/000511881</u> | Intervention - not DHT for self-management or psychological support |
| Bellvitge HUd. Feasibility and effect of a multidisciplinary telematics approach for chronic non-specific low back pain: a randomized, open-label, controlled, pilot clinical trial. Study protocol. Identifier: NCT05093543. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2021. Available from https://classic.clinicaltrials.gov/show/NCT05093543. | Unnamed intervention |
| Ben Mansouri K, Palazzo C, Dorner V, Poiradeau S, Ville I, Kadri A, et al. How new technologies can support patients adherence to home-based exercises? In: International Conference on Virtual Rehabilitation; 19-22 June 2017: Montreal, QC, Canada. | Intervention - not DHT for self-management or psychological support |
| Beresford L, Norwood T. Can physical therapy deliver clinically meaningful improvements in pain and function through a mobile app? an observational retrospective study. Arch Rehabil Res Clin Transl. 2022.4(2):100186. doi: https://dx.doi.org/10.1016/j.arrct.2022.100186 | Population – mixed and outcomes NR separately |

| Reference | Exclusion reason |
|--|----------------------------------|
| Berry A, McClellan C, Wanless B, Walsh N. A tailored app for the self-management of musculoskeletal conditions: evidencing a logic model of behavior change. JMIR Form Res. 2022.6(3):e32669. doi: <u>https://dx.doi.org/10.2196/32669</u> | Not a primary study |
| Berry A, McClellan C, Wanless B, Walsh N. Evidencing the behaviour change model underpinning a personalised and tailored app for low back pain. Physiotherapy. 2021.113(Suppl 1):e176. doi: <u>https://dx.doi.org/10.1016/j.physio.2021.10.184</u> | Not a primary study |
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| Reference | Exclusion reason |
|---|----------------------------------|
| University U. The effect of yoga on body awareness and kinesiophobia in women with chronic low back pain. Identifier: NCT05533879. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2022. Available from https://classic.clinicaltrials.gov/show/NCT05533879. | Unnamed intervention |
| US Department of Veterans Affairs. Veterans walk to beat back pain. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2008. Available from https://clinicaltrials.gov/show/NCT00694018. | Eligible non-scoped intervention |
| Utah Uo. Telehealth physical therapy for chronic back pain - ancillary study to NCT03859713. Identifier: NCT05103462. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2020. Available from https://classic.clinicaltrials.gov/show/NCT05103462. | Unnamed intervention |
| Utrecht U. E-exercise: blended physical therapy for patients with non-specific low back pain. Identifier: ISRCTN94074203. In: ISRCTN Registry [internet]. London: BioMed Central Limited: 2018. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01909306/full. | Unnamed intervention |
| VA Office of Research and Development. Selecting effective combinations of treatment for low back pain. Identifier: NCT03520387. In: Clinical.Trials.gov [internet]. Bethesda: US National Library of Medicine: 2018. Available from https://clinicaltrials.gov/show/NCT03520387. | Eligible non-scoped intervention |
| VA Office of Research and Development. Sequential and comparative evaluation of pain treatment effectiveness response (SCEPTER). Identifier: NCT04142177. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2019. Available from https://clinicaltrials.gov/show/NCT04142177. | Eligible non-scoped intervention |
| Valenciana FpeFdIISyBdIC. Efficacy study of cognitive behavioural treatment with support on communication and information technologies for the management of chronic low back pain. Identifier: NCT01802671. In: ClinicalTrials.gov [internet]. Bethesda: US National Library of Medicine: 2013. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02021726/full. | Eligible non-scoped intervention |
| Valentijn PP, Tymchenko L, Jacobson T, Kromann J, Biermann CW, AlMoslemany MA, et al. Digital health interventions for musculoskeletal pain conditions: systematic review and meta-analysis of randomized controlled trials. J Med Internet Res. 2022.24(9):e37869. doi: https://dx.doi.org/10.2196/37869 | Ineligible SR |
| Valenzuela-Pascual F, Molina F, Corbi F, Blanco-Blanco J, Gil RM, Soler-Gonzalez J. The influence of a biopsychosocial educational internet-based intervention on pain, dysfunction, quality of life, and pain cognition in chronic low back pain patients in primary care: a mixed methods approach. BMC Med Inform Decis Mak. 2015.15(97)doi: https://dx.doi.org/10.1186/s12911-015-0220-0 | Unnamed intervention |

| Reference | Exclusion reason |
|--|----------------------------------|
| van de Graaf DL, Trompetter HR, Smeets T, Mols F. Online acceptance and commitment therapy (ACT) interventions for chronic pain: a systematic literature review. Internet Interv. 2021.26:100465. doi: https://dx.doi.org/10.1016/j.invent.2021.100465 | Ineligible SR |
| van Tilburg M, Kloek C, Staal JB, Bossen D, Veenhof C. Feasibility of a stratified blended physiotherapy intervention for patients with non-specific low back pain: a mixed methods study. Physiother Theory Pract. 2022.38(2):286-98. doi: https://dx.doi.org/10.1080/09593985.2020.1756015 | Eligible non-scoped intervention |
| Verma D, Bach K, Mork PJ. External validation of prediction models for patient-reported outcome measurements collected using the selfBACK mobile app. Int J Med Inf. 2023.170:104936. doi: https://dx.doi.org/10.1016/j.ijmedinf.2022.104936 | Not a primary study |
| Vrije Universiteit Amsterdam. Back2Action. Identifier: NTR6122. In: Netherlands Trial Register [internet]. Amsterdam: The Dutch Cochrane Centre: 2016. Available from https://trialsearch.who.int/Trial2.aspx?TrialID=NTR6122. | Eligible non-scoped intervention |
| Webb M. A review of web-based applications used to support self-management of non-specific chronic low back pain. Br. 2017.11(Suppl 1):51-52. doi: https://dx.doi.org/10.1177/2049463717696602 | Ineligible SR |
| Weise H, Zenner B, Schmiedchen B, Benning L, Bulitta M, Schmitz D, et al. The effect of an app-based home exercise program on self-reported pain intensity in unspecific and degenerative back pain: pragmatic open-label randomized controlled trial. J Med Internet Res. 2022.24(10):e41899. doi: https://dx.doi.org/10.2196/41899 | Eligible non-scoped intervention |
| Werneke M, Deutscher D, Hayes D, Grigsby D, Resnik L. Associations between telerehabilitation and outcomes for patients with low back pain during the COVID-19 pandemic. Arch Phys Med Rehabil. 2022.103(12):e62. doi: https://dx.doi.org/10.1016/j.apmr.2022.08.587 | Unnamed intervention |
| Werneke MW, Deutscher D, Hayes D, Grigsby D, Mioduski JE, Resnik LJ. Is telerehabilitation a viable option for people with low back pain? associations between telerehabilitation and outcomes during the COVID-19 pandemic. Phys Ther. 2022.102(5):05. doi: https://dx.doi.org/10.1093/ptj/pzac020 | Unnamed intervention |
| West China Hospital SU. Effect of telemedicine-supported structured exercise program in patients with chronic low back pain: a randomized controlled trial. Identifier: ChiCTR2300071560. In: Chinese Clinical Trial Register [internet]. Chengdu: Chinese University of Hong Kong: 2023. Available from https://www.cochranelibrary.com/central/doi/10.1002/central/CN-02572661/full. | CT record - ongoing study |
| Woiczinski M, Schnaith F, Peuckert J, Kistler M, Pohl T, Kraft E. Effects of digitally controlled sensorimotor training on patients with low back pain. Eur Spine J. 2021.30:3328-414. doi: https://dx.doi.org/10.1007/s00586-021-07017-6 | Eligible non-scoped intervention |

| Reference | Exclusion reason |
|--|--|
| Woznica DN, Milligan M, Krymis H, Peters KC, O'Connor MI, Grant RA. Telemedical interdisciplinary care team evaluation and treatment of people with low back pain: a rsetrospective observational study. Arch Rehabil Res Clin Transl. 2023.100269. doi: https://dx.doi.org/10.1016/j.arrct.2023.100269 | Eligible non-scoped intervention |
| Xu W, Zhang Y, Wang Z, Dorsey SG, Starkweather A, Kim K. Pain self-management plus activity tracking and nurse-led support in adults with chronic low back pain: feasibility and acceptability of the problem-solving pain to enhance living well (PROPEL) intervention. BMC Nurs. 2023.22(217)doi: https://dx.doi.org/10.1186/s12912-023-01365-y | Eligible non-scoped intervention |
| Yang J, Wei Q, Ge Y, Meng L, Zhao M. Smartphone-based remote self-management of chronic low back pain: a preliminary study. J. 2019.4632946doi: https://dx.doi.org/10.1155/2019/4632946 | Eligible non-scoped intervention |
| Yoon TL, Cynn HS, Choi SA, Choi WJ, Lee JH, Choi BS. Visual feedback using a smart-phone mirroring system influences trunk muscle activity and kinematics of the trunk and pelvis in healthy and chronic low-back pain groups during arm and leg lift in quadruped position. Isokinetics and Exercise Science. 2015.23(2):117-25. doi: https://dx.doi.org/10.3233/IES-150572 | Intervention- not DHT for self-management or psychological support |
| Yueyang Affiliated to Shanghai University of Traditional Chinese Medicine ICaWMH. The research and development and promotion of appropriate technology for low back pain rehabilitation. Identifier: ChiCTR-INR-16009863. In: Chinese Clinical Trial Register [internet]. Chengdu: Chinese University of Hong Kong: 2016. Available from http://www.chictr.org.cn/showproj.aspx?proj=16702. | Population - specific LBP |
| Zadro JR, Needs C, Foster NE, Martens D, Coombs DM, Machado GC, et al. Feasibility of delivering and evaluating stratified care integrated with telehealth ('Rapid Stratified Telehealth') for patients with low back pain: protocol for a feasibility and pilot randomised controlled trial. British Journal Medicine Open. 2022.12(1):e056339. doi: https://dx.doi.org/10.1136/bmjopen-2021-056339 | Ongoing trial |
| Zheng F, Liu S, Zhang S, Yu Q, Lo WLA, Li T, et al. Does m-health-based exercise (guidance plus education) improve efficacy in patients with chronic low-back pain? A preliminary report on the intervention's significance. Trials. 2022.23(1):190. doi: https://dx.doi.org/10.1186/s13063-022-06116-z | Unnamed intervention |
| Zheng F, Zheng Y, Liu S, Yang J, Xiao W, Xiao W, et al. The effect of m-health-based core stability exercise combined with self-compassion training for patients with nonspecific chronic low back pain: a randomized controlled pilot study. Pain Ther. 2022.11(2):511-28. doi: https://dx.doi.org/10.1007/s40122-022-00358-0 | Eligible non-scoped intervention |
| Zhuo LX, Macedo LG. Feasibility and convergent validity of an activity tracker for low back pain within a clinical study: cross- sectional study. JMIR Rehabil Assist Technol. 2021.8(1):e18942. doi: https://dx.doi.org/10.2196/18942 | Eligible non-scoped intervention |

Key: CT - Clinical Trial, DHT - Digital health technology, LBP - Lower back pain, NR - Not reported, SR - Systematic review.

Appendix C – Clinical outcome tables

Table 13.4: Intermediate outcomes 1

| Study name and location | Technology name | Pain self-efficacy | Change in number appointments | |
|---|---|--------------------|--|--|
| getUBetter | | | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) | Intervention: getUBetter | NR | NR | |
| Location: UK | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) | Intervention: getUBetter Comparator: Non-app users | NR | Compared to non-users, getUBetter users required 4 times fewer GP appointments | |
| Location: UK | | | | |
| Associated publication: | | | | |
| Walker et al. (2022) Conference abstract | | | | |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) | Intervention: getUBetter | NR | NR | |
| Location: UK | | | | |
| Hinge | | | | |
| Shebib et al. (2019) (Shebib et al. 2019) | Intervention: Hinge in addition to usual care Comparator: Three digital | NR | NR | |
| Location: US Associated publications: | education articles in addition to usual care | | | |

| Study name and location | Technology name | Pain self-efficacy | Change in number appointments |
|---|---|--------------------|-------------------------------|
| ISRCTN42338218 (Hinge Health 2017) CT record | | | |
| Bailey et al. (2010) (Bailey et al. 2020) | Intervention: Hinge | NR | NR |
| Location: US | | | |
| Kaia app | | | |
| Toelle et al. (2019) (Toelle et al. 2019) | Intervention: Kaia app Comparator: Physiotherapy + online education | NR | NR |
| Location: Germany | | | |
| Priebe et al. (2020a) (Priebe et al. 2020a) | Intervention: Kaia App Comparator: Standard care | NR | NR |
| Location: Germany | | | |
| Associated publication: DRKS00015048 (Projektzentrale Rise-uP 2018) CT record | | | |
| Priebe et al. (2020b) Priebe et al. (2020c), (Priebe et al. 2020b) | Intervention: Kaia app v1 Comparator: Kaia app v2 | NR | NR |
| Location: Germany | | | |
| Jain et al. (2022) (Jain et al. 2022) | Intervention: Kaia app | NR | NR |
| Location: US | | | |
| Clement et al. (2018) (Clement et al. 2018) | Intervention : Kaia app version 0.x and 1.x | NR | NR |

| Study name and location | Technology name | Pain self-efficacy | Change in number appointments |
|---|--|--|-------------------------------|
| Location : Austria, Germany Switzerland, UK and US Associated publications: Huber et al. (2017) | | | |
| Jain et al. (2021) (Jain et al. 2021) | Intervention: Kaia app | NR | NR |
| Location: International | | | |
| SelfBACK | | | |
| Sandal et al. (2021) Location: Denmark and Norway Associated publications: Sandal et al. (2019) Protocol NCT03798288 (University of Southern Denmark 2019) CT record Overas et al. (2022) Secondary analysis Rasmussen et al. (2020) Implementation and analysis protocol Rughani et al. (2023) Secondary analysis | Intervention: selfBACK (ITT: 232 patients) Comparator: Usual care (ITT: 229 patients) | PSEQ: 3 month: selfBACK 49.2 (SD 9.9), usual care 46.6 (SD 11.2), mean difference 2.52 (95% CI, 1.04-3.99) p = 0.001 9 month: selfBACK 50.2 (SD 9.7), usual care 46.9 (AS 11.0), mean difference 3.25 (95% CI 1.71 to 4.79) | NR |
| Svendsen et al. (2022) Nested qualitative process evaluation Sandal et al. (2020) | Intervention: | PSEQ: | NR |
| (NCT03697759) | selfBACK | | |

| Study name and location | Technology name | Pain self-efficacy | Change in number appointments |
|--|---|---|-------------------------------|
| Location: Denmark and Norway | | BL (51 patients): Mean 46.8 (SD 11.1) | |
| Associated publications: NCT03697759 (University of | | 6 weeks (43 patients): Mean 50.6 (SD 8.3) | |
| Southern Denmark 2018) CT record | | Change score: 2.0 (95% CI: 0.4 to 3.6) | |
| Nordstoga et al. (2020) (Nordstoga | Intervention: selfBACK | NR | NR |
| et al. 2020) Location: Norway and UK | Stage 1: App version with only physical activity component of the intervention and a web- questionnaire to collect information to tailor self- management plans. Stage 2: An app version that incorporated 3 self- | | |
| SupportBack | management components (physical activity, exercises and education). | | |
| Geraghty et al. (2018) (Geraghty et | Intervention: SupportBack | PCS: | NR |
| al. 2018) | Arm #1 : SupportBack and usual care; (25 patients) | 3 months: Arm #1: mean 12.8 (SD: 9), mean | |
| Location: UK | Arm #2: SupportBack and | difference from BL -1.5 | |
| Geraghty 2015 (Geraghty et al. 2015) RCT protocol | physiotherapist support; (22 patients) | (95% Cl: -6.37 to 3.40); Arm #2: mean 18.63 (SD: 8.5), mean difference from | |
| Geraghty 2020 (Geraghty et al. 2020b) post-trial interviews ISRCTN31034004 (University of Southampton 2013) CT record | Arm #3: usual care (26 patients) | BL 4.2 (95% CI: -0.58 to 8.90); Arm #3 mean 14.0 (SD:11.4). | |

Key: BL – baseline, CI – confidence interval, CT – clinical trial, ITT – intention-to-treat, NR – not reported, PCS – pain catastrophising scale, PSEQ - pain selfefficacy questionnaire, SD – standard deviation.

Table 13.5: 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 |
|---|---|----------------------------------|-------------------------------|---|
| getUBetter | | | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) | Intervention: getUBetter | NR | NR | NR |
| Location: UK | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) | Intervention: getUBetter Comparator: Non-app users | NR | NR | NR |
| Location: UK | | | | |
| Associated publication: | | | | |
| Walker 2022 (Walker et al. 2022) Conference abstract | | | | |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) | Intervention: getUBetter | NR | NR | NR |
| Location: UK | | | | |
| Hinge | | | | |
| Shebib et al. (2019) | Intervention : Hinge in addition to usual care | NR | NR | NR |
| Location: US | Comparator: Three digital | | | |
| Associated publications: | education articles in addition to usual care | | | |

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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 |
|---|---|----------------------------------|----------------------------------|---|
| ISRCTN42338218 (Hinge Health 2017) CT record | | | | |
| Bailey et al. (2020) | Intervention: Hinge | NR | NR | WPAI (0-100) LBP subgroup: |
| Location: US | LBP patients : N=6,468, n patients completing =4,676 | | | BL: mean 34.12 (SD: 26.37) 12 weeks: mean 12.24 (SD: 15.58) |
| Kaia app | | | | 10.00) |
| Toelle et al. (2019) (Toelle et al. 2019) | Kaia app | NR | NR | NR |
| Location: Germany | | | | |
| Priebe et al. (2020a) (Priebe et al. 2020a) | Intervention: Kaia App Comparator: Standard care | NR | NR | NR |
| Location: Germany | | | | |
| Associated publication: | | | | |
| DRKS00015048 (Projektzentrale Rise-uP 2018) CT record | | | | |
| Priebe et al. (2020b) Priebe et al. (2020c), (Priebe et al. 2020b) Location : Germany | Intervention: Kaia app v1 Comparator: Kaia app v2 | NR | NR | NR |
| Jain et al. (2022) (Jain et al. 2022) | Intervention: Kaia app | NR | NR | NR |
| | | | | |
| Location: USA | | | | |

| Study name and location | Technology name | Time to recovery (for acute LBP) | Patient choice and preference | Work productivity/Return to full activity |
|--|--|----------------------------------|----------------------------------|---|
| Clement et al. (2018) (Clement et al. 2018) | Intervention : Kaia app version 0.x and 1.x | NR | NR | NR |
| Location : Austria, Germany Switzerland, UK and US | | | | |
| Associated publications: Huber et al. (2017) | | | | |
| Jain et al. (2021) (Jain et al. 2021) | Intervention: Kaia app | NR | NR | NR |
| Location: International | | | | |
| selfBACK | | | | |
| Sandal 2021 (NCT03697759) | Intervention: selfBACK | NR | NR | NR |
| Location : Denmark and Norway Associated publications: Sandal et al. (2019) Protocol NCT03798288 (University of Southern Denmark 2019) CT | Comparator: Usual care | | | |
| record Overas et al. (2022) Secondary analysis | | | | |
| Rasmussen et al. (2020) Implementation and analysis protocol | | | | |
| Rughani et al. (2023) Secondary analysis | | | | |

| Study name and location | Technology name | Time to recovery (for acute LBP) | Patient choice and preference | Work productivity/Return to full activity |
|---|--|----------------------------------|-------------------------------|--|
| Svendsen et al. (2022) Nested qualitative process evaluation | | | | |
| Sandal et al. (2020) (NCT03697759) Location : Denmark and Norway Associated publications: NCT03697759 (University of | Intervention: selfBACK | NR | NR | Work ability index (in 37 patients who were in full or part- time work): BL: Mean 7.3 (SD: 2.2) 6 weeks: Mean 7.4 (SD: 2.0) Change score: -0.2 (95% CI: - |
| Southern Denmark 2018) CT record | | | | 0.8 to 0.5) |
| Nordstoga et al. (2020) (Nordstoga et al. 2020) Location : Norway and UK | Intervention: selfBACK Stage 1: App version with only physical activity component of the intervention and a web- questionnaire to collect information to tailor self- management plans. Stage 2: An app version that incorporated 3 self-management components (physical activity, exercises and education). | NR | NR | NR |
| SupportBack | | T | | |
| Geraghty et al. (2018) (Geraghty et al. 2018) | Arm #1: SupportBack and usual care; Arm #2: SupportBack and | NR | NR | NR |
| Location: UK | physiotherapist support | | | |
| Geraghty et al. (2015) RCT protocol | Arm #3: usual care | | | |

| Study name and location | Technology name | Time to recovery (for acute LBP) | Patient choice and preference | Work productivity/Return to full activity |
|--|-----------------|----------------------------------|----------------------------------|---|
| Geraghty et al. (2020b) post-trial interviews | | | | |
| ISRCTN31034004 (University of Southampton 2013) CT record | | | | |

Key: BL – baseline; CI – confidence interval; CT – clinical trial; LBP – Low back pain; NR – not reported; SD – standard deviation; WPAI – work productivity and activity impairment questionnaire.

Table 13.6: Intermediate outcomes 3

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|--|--|---|--|--|--------------------------------------|--|
| getUBetter | | | | | | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) Location: UK | Design: Qualitative study Intervention: getUBetter | NR | NR | PEMAT-A/V (scored by 10 clinicians/experts and 10 patients): Understandability: 60% Actionability: 75% The vast majority of users found the app helpful and agreed that it was a much quicker way to access information to help them self manage. A few preferred to see a clinician as well as self managing the app. Only one didn't want to use the app | NR | NR | Staff reported overall positive results of using the app. Most found it was easy to give to patients but challenging to explain the context especially if time was tight. Some felt patients sometimes struggled to understand the concept, due to beliefs about best care being delivered by traditional face to face consultation. Despite this most respondents felt it enhanced the patient pathway |

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| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|--|---|--|---|--|--|--------------------------------------|--|
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublishe d) | Intervention: getUBetter (835 patients) Comparator: Non-app users (number of patients NR) | NR | | NR | NR | NR | NR |
| Location: UK Associated publication: | | | | | | | |
| Walker et al. (2022) Conference abstract | | | | | | | |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation | Intervention: getUBetter (154 patients) | NR | Patients referred who activated app: 90/154 (58%) | Patient survey: 14/154 (9%) patients responded to patient survey. Understood purpose of app: 11/14 | NR | NA | Clinician survey (15 clinicians): Agreed that Hinge: Supported self- management over whole care pathway: 12/15 |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|-------------------------------------|--------------------|--|---|--|--|--------------------------------------|--|
| Network 2022) Location: UK | | | | Found it easy to register: 10/14 Considered "easy to use" the most likable thing about the app: 9/14 (64%) Believed app provided the support and advice to help them self- manage their condition: 6/14 | | | Can support new OR recurrent conditions and be used as adjunct to physiotherapy or medication: 9/15 Helped them provide better care for patients with LBP: 11/15 Could reduce the number of follow up appointments: 11/15 Was easy to refer patients to: 10/15 73% of clinicians agreed that getUBetter helps them provide better care and 73% agreed that it helps support LBP patients with self- management of their condition. 87% of clinicians thought that |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|--|--|--|--|--|--|-------------------------------|
| | | | | | | | getUBetter was easy to use |
| Hinge | | | | | | | |
| Shebib et al. (2019) (Shebib et al. 2019) Location: US Associated publications : ISRCTN42 338218 (Hinge Health 2017) CT record | Intervention: Hinge in addition to usual care (113 patients allocated) Comparator: Three digital education articles in addition to usual care (64 allocated) | NR | Hinge (of 91 patients who began intervention): Number of workouts, mean (SD): 35.7 (28.9) Users engaging with the program per week: 75% Users active with sensor- guided exercise in weeks 1–4: 90% Users active with sensor- guided exercise in weeks 5–8: 77% Users active with sensor- | NR | NR | Did not receive intervention after randomisation:Hinge: 22 (4 received kit but unresponsive, 1 unrelated surgery before start, 17 no response to invitation)Usual care: 1 (entered into treatment due to administrative error)Lost to 12 week follow-up: Hinge Health: 19 did not complete survey 3 Discontinued for personal reasons | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|--|--|--|--|--|--|--|---------------------------|
| | | | guided exercise in weeks 9–12: 68% Offline activities logged in hours, mean (SD): 12.1 (12.5) Education articles read, mean (SD): 7.4 (4.4) Cognitive Behavioral Therapy session completed, mean (SD): 1.4 (1.2) Team posts and comments, mean (SD): 4.9 (4.7) | | | Usual care: 26 did not complete survey 1 discontinued due to herniated disc surgery | |
| Bailey et al. (2020) (Bailey et al. 2020) | Intervention: Hinge Total patients: 10,264 | Participants who completed 12 week programme (defined as completing at | Mean number of weeks engaged / 12 weeks (LBP subgroup): 8.36 (SD: 3.92). | Satisfaction score: 8.97/10 (overall patients - specific satisfaction score for LBP subgroup NR). | NR | 1,810 (27.71%) of LBP subgroup did not complete the 12 week intervention. | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|--|---|--|---|--|--|--|---------------------------|
| Location: US | LBP subgroup: 6,468 patients | least one exercise session or reading 1 educational paper in weeks 9-12): 4,676/6,486 (72.29%) | | | | | |
| Kaia app | | | | | | | |
| Toelle et al. (2019) (Toelle et al. 2019) Location : Germany | Intervention: Kaia app (53 patients allocated) Control: Physiotherapy (48 patients allocated): | Adherence to physiotherapy and online education in control group (PP: 44 patients): Of the possible 6 sessions, participants in the control group attended 89.8% sessions (mean 5.39, SD 1.22) sessions | Kaia app activity (PP: 42 patients): Within the observation period of 12 weeks, the Kaia app was used on mean 35 days (SD 22). | NR | Kaia app: None; 1 lumbar disc herniation was discovered in a patient on a routine MRI during the study, considered unrelated to intervention. Physiotherapy: None | 8 patients lost to follow-up (did not respond to questionnaire). Lost to follow- up: Kaia app: 7 (6 did not complete follow-up, 1 excluded due to pregnancy) Physiotherapy: 2 (did not complete follow-up) Discontinued intervention: | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|---|--|---|--|--|---|---------------------------|
| | | | | | | Kaia app: 4 (2 insufficient internet access, 2 unknown reasons) Physiotherapy: 2 (occupational time restrictions) | |
| Priebe et al. (2020a) (Priebe et al. 2020a) Location : Germany Associated publication: DRKS0001 5048 (Projektzen trale Rise- uP 2018) CT record | Intervention: Kaia app (PP=680) Comparator: Standard care (PP=261) | NR | Average number of days in which app used: 25 Correlation analysis between the level of pain improvement and the frequency of app usage revealed no significant correlation (r = 0.019, p > 0.05). Number of days app used by component: | NR | NR | Kaia app: Lost to follow-up (did not respond to emails): 253 Usual care: Lost to follow-up (did not respond to emails): 51 | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|--|---|--|--|--|--|---------------------------|
| | | | Physical exercise: 23 days Mindfulness: 15 days Education: 16 days | | | | |
| Priebe et al. (2020b) (Priebe et al. 2020b) Location : Germany | Intervention: Kaia app v1 (180 patients) Comparator: Kaia app v2 (153 patients) | Number of users completing 12 weeks of the app program: Kaia app v1 : 18% Kaia app v2 : 38% | NA | NR | NR | NR | NR |
| Clement et al. (2018) (Clement et al. 2018) Location : Austria, Germany, Switzerland UK and US | Intervention: Kaia app Version 0.x: 196 patients Version 1.x: 1055 patients | Users still active: v0.x : week 1 (99.0%), week 12 (54.1%), week 24 (40.3%) v1.x : Week 1 (97.5%), week 12 (54.4%), | NR | NR | NR | Discontinuations/ withdrawals: v0.x: week 1: 2/196, week 12: 3/109, week 24: 1/80. V1.x: week 1: 26/1,055, week 12: 11/312, week 24: 1/97 | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|--|--|---|--|--|--|--|
| Associated publications : Huber et al. (2017) | | week 24 (36.1%) | | | | A log-rank test revealed no significant difference in dropout for users of the 2 groups (P=0.31) | |
| Jain et al. (2022) Location : US | Intervention: Kaia app (PP: 34 patients) | NR | NR | NR | NR | 6/40 patients lost to follow-up (2 pilot patients, 4 early terminations) | Five blinded physiotherapists evaluated recorded exercises from 34 patients: |
| | | | | | | | Overall exercise execution (rated on dichotomous 0-1 acceptability scale): Kaia app Vs live physiotherapy p<0.01 |
| | | | | | | | Specific exercise execution (mean acceptability on 0-3 scale): Kaia app Vs live physiotherapy p<0.05 |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|--|--------------------|--|---|--|---|--------------------------------------|---------------------------|
| Jain et al. (2021) (Jain et al. 2021) Location : Internationa I | Kaia app | NR | 1,004,430 total active days using the Kaia app by 138,337 total users. Average number of active days per app user was 7.26. | NR | Total AE: 145 total AEs reported by 125/138,337 (0.09%) users. The rate of AEs was 0.00014 per active day. Category of AE – data available for 142 users: Increased pain 83 (58.4%), muscle issues 25 (17.6%), unpleasant sensation 19 (13.4%), headache 7 (4.9%), dizziness 4 (2.8%), sleep disturbance 3 (2.1%), surgery 1 (0.7%). Location of increased pain – data available for 83 users: Back 25 (30.1%), leg or knee 11 (13.2%), shoulder 11 (13.2%), neck 8 (9.6%), other 8 (9.6%), not specified 27 (32.5%). | NR | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|-------------------------------|--------------------|--|---|--|---|--------------------------------------|---------------------------|
| | | | | | Total AEs compared with active days on Kaia app – data available for 84 users: 0-99 days: 51 (60.7%), 100-199 days: 18 (21.4%), 200- 299 days: 6 (7.1%), 300-399 days: 6 (7.1%), 400-499 days: 2 (2.4%), 500-599 days: 1 (1.2%). AEs most frequently reported by users who had 0-99 active days on the app and less frequently by users with more active days on the app. AEs reported by gender – data available for 74 users: Female 42 (56.8%), male 31 (41.9%), unspecified 1 (1.4%) | | |
| | | | | | AEs reported by age – data available for 74 users: 1 (1.4%) < | | |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|--|---|---|---|---|---|---------------------------|
| selfBACK | | | | | 25 years (OR: 0.21, 95% CI: 0.01-1.35, P=0.15); 4 (5.4%) 25- 34 years (OR: 0.31, 95% CI: 0.08-0.95, P=0.03); 18 (24.3%) 35-44 years (OR: 1.20, 95%, CI: 0.61-2.39, P=0.63); 15 (20.3%) 45-54 years (reference); 26 (35.1%) 55-64 years (OR: 2.53, 95%, CI: 1.36-4.84, P=0.002); 8 (10.8%) 65-75 years (OR:1.97, 95% CI: 0.74-4.77, P=0.13); 2 (2.7%) >75 years (OR: 4.36, 95% CI: 1.07- 13.26, P=0.02) | | |
| Sandal 2021 (NCT03697 759) Location : Denmark | Intervention: selfBACK (232 patients) Comparator: Usual care (229 patients) | selfBACK: 181/232 (78%) adhered to selfBACK (adherence was defined as creating ≥6 | NR | Global Perceived Effect scale score, range: -5 to 5 (scores above 0 points indicating improvement [anchor: "very much better"] and | selfBACK: 0 Usual care: 0 NR | Lost to follow up selfBACK: 196 at 6 weeks 209 at 3 months 167 at 6 months 170 at 9 months | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|--------------------|--|---|--|--|---|---------------------------|
| and Norway Associated publications : Sandal et al. (2019) Protocol NCT03798 288 (University of Southern Denmark 2019) CT record Overas et al. (2022) Secondary analysis Rasmussen et al. (2020) Implementa tion and analysis protocol Rughani et al. (2023) | | self- management plans during the first 12 weeks after randomization) Usual care : NR Participants described becoming familiarized with the exercises over time and as a result failed to record them in the app, thus limiting its use. Many participants reported only using the app when LBP flared up and forgetting to use it when | | scores below 0 points indicating worsening [anchor: "very much worse"])): 3 month: selfBACK : Mean 1.2 (SD 1.9) Usual care: Mean 2.0 (SD 1.9) Mean difference: 0.70 (95% CI 0.39 to 1.01) p<0.001 9 month : selfBACK: Mean 1.3 (SD 2.2) Usual care: Mean 2.2 (SD 2.0) Mean difference : 0.81 (95% CI 0.49 to 1.15) | | Usual care: Lost to follow up: 172 at 6 weeks 190 at 3 months 182 at 6 months 182 at 9 months Discontinuations : selfBACK: 4 at 6 weeks 5 at 3 months 14 at 6 months 3 at 9 months Usual care: 11 at 6 weeks 5 at 3 months 2 at 9 months 2 at 9 months | |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|--|---------------------------|--|---|---|--|---|---------------------------|
| Secondary analysis Svendsen et al. (2022) Nested qualitative process evaluation | | the pain decreased. Some participants reported that too much pain limited engagement with the selfBACK app. | | | | | |
| Sandal et al. (2020) (NCT03697 759) Location: Denmark and Norway Associated publications : NCT03697 759 (University of Southern Denmark | Intervention: selfBACK | NR | App use (51 patients, mean (range)): Time spent in app (minutes) mean 134: (range 0 to 889) Total no. of visits mean 65: (range 1 to 188) No. of days visiting the app: mean 22 (range 1 to 47)* No. of visits pr. Day on days the app was visited: | PASS at 6 weeks: Yes: 20 (47) No: 23 (53) Global Perceived Effect at 6 weeks (43 patients): Very much worse: 2 (5) Somewhat worse: 0 (0) Slightly worse: 3 (7) No change: 13 (30) Slightly better: 14 (33) | NR | 8 patients lost to follow-up (did not respond to questionnaire). Authors report that 0 patients discontinued intervention. | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|--|--|--|--|---|--|--|---------------------------|
| 2018) CT record | | | mean 3 (range 1 to 5) No. of self- management plans created: mean 4 (range 0 to 8) | Somewhat better: 8 (19) Very much better: 1 (2) | | | |
| Nordstoga et al. (2020) (Nordstoga et al. 2020) Location : Norway and UK | Intervention: selfBACK Stage 1: App version with only physical activity component of the intervention and a web- questionnaire to collect information to tailor self- management plans. (16 patients completing questionnaire) Stage 2: An app version | NR | Step count goal (stage 1): Average step count goal was 7,004 steps per day (SD: 2932, range 3,000- 12,500). Average step count achieved was 5,469 steps per day (SD 4,354, range: 133-20,791). App usage (stage 1): Participants opened app mean 6.2 times per day (SD: | Stage 1: 11/16 (69%) would download the selfBACK app and 10/16 (63%) would recommend it to a friend. Stage 2: 9 (90%) would like to use the selfBACK app frequently. | NR | Stage 1: 0 dropouts Stage 2: 2/10 participants stopped using the app. 1 due to persistent log-in difficulties and 1 due to not receiving any self- management plan for exercises after week 1. | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|-------------------------------|---|--|---|--|--|--------------------------------------|---------------------------|
| | that incorporated 3 self- management components (physical activity, exercises and education). (10 patients completing questionnaire) | | 11.8, range 0- 95). Notifications (stage 1): In total 569 notifications sent during study. Participants received mean 1.8 motivational notifications per day (SD: 2.4, rang 0-10). Participants opened 42% (239/569) of received notifications. Notifications sent at the start of the day opened most frequently. 215 (90%) of opened notifications were liked, 19 (8%) were | | | | |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) disliked and no sentiment was expressed for 5 (2%). Notifications regarding full goal achievement were most | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|---|--|--|--|---|--|---------------------------|
| SupportBac | k | | frequently liked. | | | | |
| Geraghty et al. (2018) (Geraghty et al. 2018) Location: UK Associated publications Geraghty et al. (2015) RCT protocol Geraghty et al. (2020b) | Arm #1: SupportBack and usual care (30 patients allocated, 25 analysed) Arm #2: SupportBack and physiotherapis t support (29 patients allocated, 22 analysed) Arm #3: usual care (28 patients | Adherence: Patients not progressing beyond session 1 of 6: SupportBack plus usual care: 8 (29.6%) SupportBack and telephone support plus usual care: 3 (11.1%) in the | NR | NR | 6 hospital admissions reported (2 SupportBack and usual care, 2 SupportBack and physiotherapist support, 2 usual care). Reported that it is very unlikely the SupportBack intervention was a factor. | Arm #1: Lost to follow-up: 2 Arm #2: Lost to follow-up: 4 Withdrew: 1 Arm #3: Lost to follow-up: 5 Withdrew: 2 | NR |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|---|----------------------------|---|---|--|--|--------------------------------------|---------------------------|
| post-trial interviews ISRCTN31 034004 (University of Southampt on 2013) CT record | allocated, 26 analysed) | Patients completing all 6 sessions: SupportBack plus UC: 32% SupportBack and Telephone plus UC: 41% Difference not reported. Times a day spent doing a back exercise or going for a walk: SupportBack and usual care (16 patients): 0 (0%) never started, 2 (12.5%) 1 day, 5 (31.3%) 2 to 3 days, 4 (25.0%) 4 to 5 days, 5 (31.3%) every day. | | | | | |

| Study name and location | Technology name | Intervention adherence and completion | Engagement measures (indicators of app use over study period) | Treatment satisfaction and engagement (patient opinion) | Intervention- related adverse effect | Withdrawals/ discontinuatio ns | Clinician satisfaction |
|-------------------------------|--------------------|--|---|--|--|--------------------------------------|---------------------------|
| | | SupportBack and physiotherapis t support (19 patients): 0 (0%) never started, 1 (5.3%) 1 day, 2 (10.5%) 2 to 3 days, 7 (36.8%) 4 to 5 days, 9 (47.4%) every day. Usual care (14 patients): 2 (14.3%) never started, 1 (7.1%) 1 day, 2 (14.3%) 2 to 3 days, 5 (35.7%) 4 to 5 days, 4 (28.6%) every day. | | | | | |

Key: AE – adverse event, CI – confidence interval, CT – clinical trial, HCP – healthcare practitioner, LBP – Low back pain, MRI – magnetic resonance imaging, NR – not reported, OR – odds ratio, PEMAT-A/V – patient education materials assessment tool, PP – per protocol, SD – standard deviation, UC – usual care, Vs – Versus.

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Table 13.7 - Clinical outcomes 1

| Study name and location | Technology name | Physiotherapy referrals | Treatment waiting list | Self-removal from waiting list | | | |
|---|--|-------------------------|------------------------|--------------------------------|--|--|--|
| getUBetter | getUBetter | | | | | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) Location: UK | Design : Qualitative study Intervention : getUBetter | NR | NR | NR | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) | Intervention: getUBetter (835 patients) Comparator: Non-app users (number of patients NR) | | NR | NR | | | |
| Location: UK Associated publication: Walker et al. (2022) Conference abstract | | | | | | | |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) | Intervention: getUBetter | NR | NR | NR | | | |
| Location: UK | | | | | | | |
| Hinge | | <u>.</u> | | · | | | |

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| Study name and location | Technology name | Physiotherapy referrals | Treatment waiting list | Self-removal from waiting list |
|---|---|-------------------------|------------------------|--------------------------------|
| Shebib et al. (2019) (Shebib et al. 2019) Location : US Associated publications: ISRCTN42338218 (Hinge Health 2017) CT record | Intervention: Hinge in addition to usual care (PP: 69 patients) Comparator: Three digital education articles in addition to usual care (PP: 36 patients) | NR | NR | NR |
| Bailey et al. (2020) (Bailey et al. 2020) Location: US | Intervention: Hinge (N=6,468, n patients completing=4,676) | NR | NR | NR |
| Kaia app | | | | |
| Toelle et al. (2019) (Toelle et al. 2019) | Intervention: Kaia app (PP: 42 patients) | NR | NR | NR |
| Location: Germany | Comparator : Physiotherapy (PP: 44 patients) | | | |
| Priebe et al. (2020a) (Priebe et al. 2020a) Location : Germany | Intervention: Kaia app (PP: 680 patients) Comparator: Standard care (PP 261 patients) | NR | NR | NR |
| Associated publication: DRKS00015048 (Projektzentrale Rise- uP 2018) CT record | | | | |

| Study name and location | Technology name | Physiotherapy referrals | Treatment waiting list | Self-removal from waiting list |
|---|--|-------------------------|------------------------|--------------------------------|
| Priebe et al. (2020b) (Priebe et al. 2020b) | Intervention: (180 patients) | NR | NR | NR |
| Location: Germany | Comparator : Kaia app v2 (153 patients) | | | |
| Jain et al. (2022) (Jain et al. 2022) | Intervention: Kaia app | NR | NR | NR |
| Location: US | | | | |
| Clement et al. (2018) | Intervention: Kaia app version 0.x and 1.x | NR | NR | NR |
| Location : Austria, Germany Switzerland, UK and US | | | | |
| Associated publications: | | | | |
| Huber et al. (2017) | | | | |
| Jain et al. (2021) (Jain et al. 2021) | Kaia app | NR | NR | NR |
| Location: International | | | | |
| selfBACK | | | | |
| Sandal et al. (2021) (NCT03697759) | Intervention: selfBACK Comparator: | NR | NR | NR |
| | Usual care | | | |

| Study name and location | Technology name | Physiotherapy referrals | Treatment waiting list | Self-removal from waiting list |
|--|---------------------------|-------------------------|------------------------|--------------------------------|
| Location: Denmark and Norway | | | | |
| Associated publications: Sandal et al. (2019) Protocol | | | | |
| NCT03798288 (University of Southern Denmark 2019) CT record | | | | |
| Overas et al. (2022) Secondary analysis | | | | |
| Rasmussen et al. (2020) Implementation and analysis protocol | | | | |
| Rughani et al. (2023) Secondary analysis | | | | |
| Svendsen et al. (2022) Nested qualitative process evaluation | | | | |
| Sandal et al. (2020) (NCT03697759) | Intervention: selfBACK | NR | NR | NR |
| Location: Denmark and Norway | | | | |
| Associated publications: | | | | |

| Study name and location | Technology name | Physiotherapy referrals | Treatment waiting list | Self-removal from waiting list |
|---|--|-------------------------|------------------------|--------------------------------|
| NCT03697759 (University of Southern Denmark 2018) CT record | | | | |
| Nordstoga et al. (2020) (Nordstoga et al. 2020) | Intervention: selfBACK | NR | NR | NR |
| Location: Norway and UK | Stage 1: App version with only physical activity component of the intervention and a web-questionnaire to collect information to tailor self-management plans. Stage 2: An app version that incorporated 3 self- management components (physical activity, exercises and education). | | | |
| SupportBack | | | | |
| Geraghty et al. (2018) (Geraghty et al. 2018) Location : UK Associated publications: | Arm #1: SupportBack and usual care; Arm #2: SupportBack and physiotherapist support; Arm #3: usual care | NR | NR | NR |

| Study name and location | Technology name | Physiotherapy referrals | Treatment waiting list | Self-removal from waiting list |
|---|-----------------|-------------------------|------------------------|--------------------------------|
| Geraghty et al. (2015) RCT protocol | | | | |
| Geraghty et al. (2020a), (Geraghty et al. 2020b) post-trial interviews | | | | |
| ISRCTN31034004 (University of Southampton 2013) CT record | | | | |

Key: BL – baseline, CT – clinical trial, ITT – intention-to-treat, NR – not reported, PP – per protocol.

Table 13.8: Clinical outcomes 2

| Study name and location | Technology name | Reduced pharmacological management | Reoccurrence of LBP | Reduced imaging referrals |
|---|---|------------------------------------|---------------------|---------------------------|
| getUBetter | | I | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) | Intervention: getUBetter | NR | NR | NR |
| Location: UK | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) Location: UK Associated publication: Walker et al. (2022) Conference abstract | Intervention: getUBetter (835 patients) Comparator: Non- app users (number of patients NR) | | NR | NR |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) | Intervention: getUBetter | NR | NR | NR |
| Hinge | | | | · · |
| Shebib et al. (2019) (Shebib et al. 2019) | Intervention: Hinge in addition to usual care Comparator: Three | NR | NR | NR |

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| Study name and location | Technology name | Reduced pharmacological management | Reoccurrence of LBP | Reduced imaging referrals |
|---|---|------------------------------------|---------------------|---------------------------|
| Location: US Associated publications: ISRCTN42338218 (Hinge Health 2017) CT record | digital education articles in addition to usual care | | | |
| Bailey et al. (2020) (Bailey et al. 2020) Location: US | Intervention: Hinge | NR | NR | NR |
| Kaia app | | | | |
| Toelle et al. (2019) (Toelle et al. 2019) Location: Germany | Intervention: Kaia app Comparator: Physiotherapy | NR | NR | NR |
| Priebe et al. (2020a) (Priebe et al. 2020a) Location : Germany Associated publication: DRKS00015048 (Projektzentrale Rise-uP 2018) CT record | Intervention: Kaia app Comparator: Standard care | NR | NR | NR |
| Priebe et al. (2020b) (Priebe et al. 2020b) Location : Germany | Intervention: Kaia app (180 patients) Comparator: Kaia app v2 (153 patients) | NR | NR | NR |

| Study name and location | Technology name | Reduced pharmacological management | Reoccurrence of LBP | Reduced imaging referrals |
|---|--|------------------------------------|---------------------|---------------------------|
| Jain et al. (2022) | Intervention: Kaia app | NR | N | NR |
| Location: US | | | | |
| Clement et al. (2018) | Intervention: Kaia app version 0.x and | NR | NR | NR |
| Location : Austria, Germany Switzerland, UK and US | 1.x | | | |
| Associated publications: Huber et al. (2017) | | | | |
| Jain et al. (2021) | Intervention: Kaia app | NR | NR | NR |
| Location: International | | | | |
| selfBACK | | | | |
| Sandal et al. (2021) (NCT03697759) | Intervention: selfBACK | NR | NR | NR |
| Location : Denmark and Norway | Comparator : Usual care | | | |
| Associated publications: Sandal et al. (2019) Protocol | | | | |
| NCT03798288 (University of Southern Denmark 2019) CT record | | | | |

| Study name and location | Technology name | Reduced pharmacological management | Reoccurrence of LBP | Reduced imaging referrals |
|--|--|------------------------------------|---------------------|---------------------------|
| Overas et al. (2022) Secondary analysis | | | | |
| Rasmussen et al. (2020) Implementation and analysis protocol | | | | |
| Rughani et al. (2023) Secondary analysis | | | | |
| Svendsen et al. (2022) Nested qualitative process evaluation | | | | |
| Sandal et al. (2020) (NCT03697759) | Intervention: selfBACK | NR | NR | NR |
| Location : Denmark and Norway | | | | |
| Associated publications: | | | | |
| NCT03697759 (University of Southern Denmark 2018) CT record | | | | |
| Nordstoga et al. (2020) (Nordstoga et al. 2020) | Intervention: selfBACK | NR | NR | NR |
| Location: Norway and UK | Stage 1 : App version with only physical activity component of the intervention and a web-questionnaire to collect information to tailor self- management plans. | | | |

| Study name and location | Technology name | Reduced pharmacological management | Reoccurrence of LBP | Reduced imaging referrals |
|---|--|------------------------------------|---------------------|---------------------------|
| | Stage 2 : An app version that incorporated 3 self- management components (physical activity, exercises and education). | | | |
| SupportBack | | | | |
| Geraghty et al. (2018) (Geraghty et al. 2018) | Arm #1: SupportBack and usual care | NR | NR | NR |
| Location: UK Geraghty et al. (2015) RCT protocol Geraghty et al. (2020b)Geraghty 2020 (Geraghty et al. 2020b) ISRCTN31034004 (University of Southampton 2013) CT record | Arm #2: SupportBack and physiotherapist support; Arm #3: usual care | | | |

Key: CT – clinical trial, LBP – Low back pain, NR – not reported.

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Table 13.9: Clinical outcomes 3

| Study name and location | Technology name | Discharge rate | Surgical referrals | Emergency department attendances |
|--|--|----------------|--------------------|----------------------------------|
| getUBetter | | | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) | Intervention: getUBetter | NR | NR | NR |
| Location: UK | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) Location: UK Associated publication: Walker et al. (2022) Conference abstract | Intervention: getUBetter Comparator: Non-app users | NR | NR | NR |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) Location : UK | Intervention: getUBetter | NR | NR | NR |
| Hinge | 1 | | | |

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| Technology name | Discharge rate | Surgical referrals | Emergency department attendances |
|--|--|--|--|
| Intervention: Hinge in addition to usual care (ITT: 113 patients; PP: 69 patients) Comparator: Three digital education articles in addition to usual care (ITT: 64 patients; PP: 36 patients) | NR | VAS surgery interest (ITT): Hinge: BL: Mean 0.894 (SD 1.71) 12 weeks: Mean 0.619 (SD 1.35) Usual care: BL: 1.39 (SD 2.55) 12 weeks: Mean 1.53 (SD 2.67) Mean difference: -0.4 (95% CI -0.7, -0.1) p=0.01 VAS surgery interest (PP): Hinge: BL: Mean 0.681 (SD 1.59) 12 weeks: Mean 0.333 (SD 0.918) Usual care: BL: 0.639 (SD 1.31) 12 weeks: Mean 0.972 (SD 1.89) Mean difference: -0.7 (95% CI -1.2, -0.2) p=0.06 | NR |
| Intervention : Hinge LBP patients : n=6,468, n patients completing = | NR | Patient perception 1-year surgery likelihood (0-100) LBP subgroup: BL: 9.07 (SD: 17.98) | NR |
| | Intervention: Hinge in addition to usual care (ITT: 113 patients; PP: 69 patients) Comparator: Three digital education articles in addition to usual care (ITT: 64 patients; PP: 36 patients) | Intervention: Hinge in addition to usual care (ITT: 113 patients; PP: 69 patients) NR Comparator: Three digital education articles in addition to usual care (ITT: 64 patients; PP: 36 patients) NR Intervention: Hinge LBP patients: n=6,468, n NR | Intervention: Hinge in addition to usual care (ITT: 113 patients; PP: 69 patients)NRVAS surgery interest (ITT): Hinge: BL: Mean 0.894 (SD 1.71) 12 weeks: Mean 0.619 (SD 1.35)Comparator: Three digital education to usual care (ITT: 64 patients; PP: 36 patients)NRUsual care: BL: 1.39 (SD 2.55) 12 weeks: Mean 1.53 (SD 2.67) Mean difference: -0.4 (95% CI -0.7, -0.1) p=0.01VAS surgery interest (PP): Hinge: BL: Mean 0.681 (SD 1.59) 12 weeks: Mean 0.333 (SD 0.918)Usual care: BL: 0.639 (SD 1.31) 12 weeks: Mean 0.972 (SD 1.89) Mean difference: -0.7 (95% CI -1.2, -0.2) p=0.06Intervention: Hinge LBP patients: n=6,468, nNRPatient perception 1-year surgery likelihood (0-100) LBP subgroup: |

| Study name and location | Technology name | Discharge rate | Surgical referrals | Emergency department attendances |
|--|---|----------------|--------------------|----------------------------------|
| Toelle et al. (2019) (Toelle et al. 2019) | Intervention: Kaia app Comparator: Physiotherapy | NR | NR | NR |
| Location: Germany | | | | |
| Priebe et al. (2020a) (Priebe et al. 2020a) | Intervention: Kaia app Comparator: Standard care | NR | NR | NR |
| Location: Germany | | | | |
| Associated publication: | | | | |
| DRKS00015048 (Projektzentrale Rise- uP 2018) CT record | | | | |
| Priebe et al. (2020b) | Intervention: Kaia app (180 | NR | NR | NR |
| (Priebe et al. 2020b) Location: Germany | patients) Comparator: Kaia app v2 (153 patients) | | | |
| Jain et al. (2022) | Intervention: Kaia app | NR | NR | NR |
| Location: US | | | | |
| Clement et al. (2018) (Clement et al. 2018) | Intervention: Kaia app version 0.x and 1.x | NR | NR | NR |
| Location: Austria, Germany Switzerland, UK and US | | | | |
| Associated publications: Huber et al. (2017) | | | | |

| Study name and location | Technology name | Discharge rate | Surgical referrals | Emergency department attendances |
|--|--|----------------|--------------------|----------------------------------|
| Jain et al. (2021)Jain 2021 (Jain et al. 2021) | Intervention: Kaia app | NR | NR | NR |
| Location: International | | | | |
| selfBACK | | | | |
| Sandal et al. (2021) (NCT03697759) | Intervention: selfBACK Comparator: Usual care | NR | NR | NR |
| Location: Denmark and Norway | | | | |
| Associated publications: Sandal et al. (2019) Protocol | | | | |
| NCT03798288 (University of Southern Denmark 2019) CT record | | | | |
| Overas et al. (2022) Secondary analysis | | | | |
| Rasmussen et al. (2020) (Rasmussen et al. 2020) Implementation and analysis protocol | | | | |
| Rughani et al. (2023) Secondary analysis | | | | |
| Svendsen et al. (2022) Nested qualitative process evaluation | | | | |

| Study name and location | Technology name | Discharge rate | Surgical referrals | Emergency department attendances |
|---|---|----------------|--------------------|----------------------------------|
| Sandal et al. (2020) (NCT03697759) | Intervention: selfBACK | NR | NR | NR |
| Location: Denmark and Norway Associated publications: NCT03697759 (University of Southern Denmark 2018) CT record | | | | |
| Nordstoga et al. (2020) (Nordstoga et al. 2020) Location : Norway and UK | Intervention: selfBACK Stage 1: App version with only physical activity component of the intervention and a web- questionnaire to collect information to tailor self- management plans. Stage 2: An app version that incorporated 3 self- management components (physical activity, exercises and education). | NR | NR | NR |
| SupportBack | | | | |
| Geraghty et al. (2018) | Arm #1: SupportBack and usual care | NR | NR | NR |
| Location: UK | | | | |

| Study name and location | Technology name | Discharge rate | Surgical referrals | Emergency department attendances |
|--|--|----------------|--------------------|-------------------------------------|
| Associated publications; | Arm #2: SupportBack and | | | |
| Geraghty et al. (2015) RCT protocol | physiotherapist support; Arm #3 : usual care | | | |
| Geraghty et al. (2020b) post-trial interviews | | | | |
| ISRCTN31034004 (University of Southampton 2013) CT record | | | | |

Key: BL – baseline, CI – confidence interval, CT – clinical trial, ITT – intention-to-treat, LBP – Low back pain, NR – not reported, PP – per protocol.

Table 13.10: Patient reported outcomes 1

| Study name and location | Technology name | Functional outcomes | Pain | | |
|---|---|-------------------------------|-------------------------------|--|--|
| getUBetter | | | | | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) | Intervention: getUBetter | NR | NR | | |
| Location: UK | | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) | Intervention: getUBetter Comparator: Non-app users | NR | NR | | |
| Location: UK | | | | | |
| Associated publication: | | | | | |
| Walker et al. (2022) Conference abstract | | | | | |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) | Intervention: getUBetter | NR | NR | | |
| Location: UK | | | | | |
| Hinge | | | | | |
| Shebib et al. (2019) (Shebib et | Intervention: Hinge in | MvK, disability (ITT): | MvK 0-100, pain (ITT): | | |
| al. 2019) | addition to usual care | Hinge: | Hinge Health: | | |
| | (ITT: 113 patients; PP: 69 patients) | BL: Mean 34.3 (SD 23.1) | BL: Mean 51.1 (SD 17.8) | | |
| Location: US | Comparator: Three | 12 weeks: Mean 21.5 (SD 19.6) | 12 weeks: Mean 33.8 (SD 21.6) | | |

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| Study name and location | Technology name | Functional outcomes | Pain |
|--------------------------|-------------------------------------|--|---|
| Associated publications: | digital education articles | Usual care: | Usual care: |
| ISRCTN42338218 (Hinge | in addition to usual care | BL: Mean 40.3 (SD 24) | BL: Mean 51.4 (SD 17.4) |
| Health 2017) CT record | (ITT: 64 patients; PP: 36 patients) | 12 weeks: Mean 40.5 (SD 25.7) | 12 weeks: Mean 50.5 (SD 21.4) |
| | patients) | Mean difference: -13 (95% CI -19.3, -6.7) p<0.001 | Mean difference HH Vs control: −16.4 (95% CI −22, −10.9) p<0.001 |
| | | MvK, disability (PP): | MvK 0-100, pain (PP): |
| | | Hinge: | Hinge: |
| | | BL: Mean 33.1 (SD 24.3) | BL: Mean 48.8 (SD: 17.8) |
| | | 12 weeks: Mean 15 (SD 15.5) | 12 weeks: Mean 23.4 (SD: 16.1) |
| | | Usual care: | Usual care: |
| | | BL: 34.2 (SD 20.2) | BL: 47.5 (16.1) |
| | | 12 weeks: 37.3 (SD 24.3) | 12 weeks: 49.1 (21.4) |
| | | Mean difference HH Vs control: -21.3 95% CI -30.8, -11.7) p<0.001 | Mean difference HH Vs control: -26.9 (95% CI: -33.8, -20) p<0.001 |
| | | | VAS pain score 0-100 past 24 hours (ITT): |
| | | | Hinge: |
| | | | BL: 46.3 (SD 20.9) |
| | | | 12 weeks: 25.8 (SD 21.4) |
| | | | Usual care: |
| | | | BL: 45.4 (SD 20.8) |
| | | | 12 weeks: 40.8 (SD 23.2) |
| | | | Mean difference: -16 (95% CI: -22.5, -9.4) p<0.001 |
| | | | VAS pain score 0-100 past 24 hours (PP): |

| Study name and location | Technology name | Functional outcomes | Pain |
|-------------------------|---------------------------------------|---------------------|---|
| | | | Hinge: |
| | | | BL: Mean 43.6 (SD 20.5) |
| | | | 12 weeks: 16.5 (SD 15.5) |
| | | | Usual care: |
| | | | BL: 42.6 (SD 19.4) |
| | | | 12 weeks: 39.2 (SD 23.6) |
| | | | Mean difference: −23.7 (95% CI: −31.9, −15.5) p<0.001 |
| | | | % patients with ≥ 15 point change in VAS pain in PP population: |
| | | | Hinge: 48/69 (70%); Usual care: 8/36 (22%) p<0.001 |
| | | | % patients with ≥ 30% VAS pain reduction: |
| | | | Hinge: 56/69 (81%); Usual care: 10/36 (28%) p<0.001 |
| | | | % patients with ≥ 30% <i>or</i> 15 point pain reduction: Hinge: 56/69 (81%), Usual care: 11/36 (31%) p<0.001 |
| Bailey et al. (2020) | Intervention: Hinge | NR | VAS Pain 0-100 (past 24 hours): |
| Location: US | (LBP patients: N=6,468, n patients | | Mean difference 12 weeks: reduction of 31.58 points (68.9%) p=NR |
| | completing=4,676) | | MvK pain 0-100: |
| | | | Mean decrease at 12 weeks Vs BL: 51.4% (8.20 points, p<0.001) p=NR |
| Kaia app | 1 | 1 | |

| Study name and location | Technology name | Functional outcomes | Pain |
|-------------------------|---|--|--|
| Toelle et al. (2019) | Intervention : Kaia app (PP: 42 patients) | Hannover Functional Ability Questionnaire (HFAQ): | NRS 1-10 (index score, mean of current, maximum and average pain intensity in prior 4 weeks): |
| Location: Germany | Comparator: Physiotherapy (PP: 44 patients) | BL: Kaia app, mean 0.79 (SD 0.14), physiotherapy, mean 0.76 (SD 0.15) 6 weeks: Kaia app, mean 0.77 (SD 0.17), physiotherapy, mean 0.74 (SD 0.12) p = NR 12 weeks: Kaia app, mean 0.80 (SD 0.12), physiotherapy, mean 0.75 (SD 0.23) p = not significant | Within group BL to 6 weeks: Kaia app 5.10 (1.07) to 4.33 (1.11), p<0.01. Control 5.41 (1.15) to 4.09 (1.42), p<0.01). Within group 6 to 12 weeks: Kaia app 4.33 (1.11) to 2.70 (1.51), p<0.01. Control 4.09 (1.42) to 3.40 (1.63), p<0.01). Between group 6 weeks: Kaia app 4.33 (1.11), control 4.09 (1.42), p>0.05. Between group 12 weeks: Kaia app 2.70 (1.51), control 3.40 (1.63), p=0.021. Between-group difference in pain reduction = -2.0 (p > 0.05). Graded Chronic Pain Scale (calculated for subgroup of chronic LBP, differences not tested for significance): BL: Grade I Kaia app 18 patients (52.9%), physiotherapy 9 patients (27.3%) Grade II Kaia app 13 patients (38.2%), physiotherapy 17 patients (51.5%) Grade III Kaia app 3 patients (8.8%), physiotherapy 5 patients (15.2%) Grade IV Kaia app 0 patients, physiotherapy 2 patients (6.1%) |
| | | | 6 weeks: |

| Study name and location | Technology name | Functional outcomes | Pain |
|---|--|---|---|
| | | | Grade I Kaia app 19 patients (55.9%), physiotherapy 19 patients (54.3%) |
| | | | Grade II Kaia app 14 patients (41.2%), physiotherapy 13 patients (37.1%) |
| | | | Grade III Kaia app 1 patient (2.9%), physiotherapy 3 patients (8.6%) |
| | | | Grade IV Kaia app 0 patients, physiotherapy 0 patients |
| | | | 12 weeks: |
| | | | Grade I Kaia app 27 patients (84.4%), physiotherapy 22 patients (62.9%) |
| | | | Grade II Kaia app 5 patients (15.6%), physiotherapy 12 patients (34.3%) |
| | | | Grade III Kaia app 0 patients, physiotherapy 1 patients (2.9%) |
| | | | Grade IV Kaia app 0 patients, physiotherapy 0 patients |
| | | | Patients reporting no current back pain (differences not tested for significance): |
| | | | 6 weeks : Kaia app 3 patients, physiotherapy 4 patients |
| | | | 12 weeks: Kaia app 14 patients, physiotherapy 7 patients |
| Priebe et al. (2020a) (Priebe et al. 2020a) | Intervention: Kaia app (PP: 680 patients) | Hannover Functional Ability Questionnaire | NRS 0-10 (index score, mean of current, maximum and average pain intensity in prior 4 weeks): |
| Location: Germany | Comparator: Standard care (PP: 261 patients) | (0% - 100%, difference not tested statistically): | Kaia app : mean reduction at 3 months Vs BL: from mean 5.22 (SD 1.71) to 3.37 (SD 2.35) p<0.001. |
| Associated publication: | | BL: | |

| Study name and location | Technology name | Functional outcomes | Pain |
|---|---|---|---|
| DRKS00015048 (Projektzentrale Rise-uP 2018) CT record | | Kaia app: Mean 72.4% (SD 18.6%) Usual care: 78.1% (SD 17.6%) | Usual care : mean reduction at 3 months Vs BL: from mean 5.2 (SD 1.74) to 4.02 (SD 2.19) p<0.001. |
| | | 3 months: Kaia app: 80.2% (SD 18.1%) Usual care: 78.3% (SD 17.8%) | Percentage change in mean pain intensity score: Kaia app : -33.3% Usual care: -14.3% p<0.001 |
| | | | Pain response (% patients experiencing % change in pain score, differences not tested statistically): <15%: Kaia app 35.1 % Vs usual care 44.1% 15-29%: Kaia app 15.2% Vs usual care 20.0% 30-49%: Kaia app 16.1% Vs usual care 16.1% >50%: Kaia app 34.0% Vs usual care 20.0% |
| Priebe et al. (2020b) (Priebe et al. 2020b) Location: Germany | Intervention: Kaia app v1 (180 patients) Comparator: Kaia app v2 (153 patients) | NR | NRS 0-10: BL: Kaia app v1: Mean 4.80 (SD 1.59) Kaia app v2: Mean 4.20 (SD 1.98) 12 weeks: Kaia app v1 (18% of patients): Mean 3.75 (SD 1.76) Change from BL: Mean -1.04 (SD 2.12) p<0.001 |
| Jain et al. (2022) (Jain et al. 2022) | Intervention: Kaia app | NR | NR |

| Study name and location | Technology name | Functional outcomes | Pain |
|---|--|--|---|
| Location: US | | | |
| Clement et al. (2018) (Clement et al. 2018) | Intervention: Kaia app | NR | NRS 0-10 (change from BL not tested for significance): |
| Location: Austria, Germany Switzerland, UK and US | Version 0.x: 196 patients Version 1.x: 1,055 | | v0.x: BL mean 4.32 (SD: 1.50), 12 week mean 3.80 (SD: 2.17), 24 week mean 3.48 (2.09) |
| Associated publications: Huber et al. (2017) | patients | | v1.x: BL mean 4.19 (SD: 1.55), week 12 mean 3.09 (SD: 1.78), week 24 mean 2.95 (SD: 2.17) |
| Jain et al. (2021) (Jain et al. 2021) | Intervention: Kaia app | NR | NR |
| Location: International | | | |
| selfBACK | | | |
| Sandal et al. (2021) | Intervention: | Mean RMDQ: | NRS (0-10): |
| (NCT03697759) | selfBACK (ITT: 232 | 3 month: selfBACK 6.7 (SD 4.7), | Average pain intensity in preceding week: |
| Location: Denmark and | patients) | usual care 7.4 (SD 5.4), mean difference -0.79 (95%CI -1.51 to - | 3 months: |
| Norway | Comparator : Usual care (ITT: 229 | 0.06) p=0.03. | selfBACK 3.3 (SD 2.2), usual care 3.9 (SD 2.4), mean difference -0.62 (95% CI, -0.99 to -0.26) p= 0.001 |
| Associated publications: | patients) | 9 month: selfBACK 6.0 (SD 5.3), | difference -0.02 (95% Ci, -0.99 to -0.26) p- 0.001 |
| Sandal et al. (2019) Protocol | , , | usual care 6.9 (SD 5.6), mean | SelfBACK 3.0 (SD 2.3), usual care 3.7 (SD 2.4), mean |
| NCT03798288 (University of Southern Denmark 2019) CT record | | difference -0.88 (95 % CI -1.64 to - 0.11) | difference -0.69 (95% CI, -1.07 to -0.30) |
| Overas et al. (2022) | | Proportion reporting improvement | Worst pain intensity in preceding week: |
| Secondary analysis | | (>4 point improvement) (PP | 3 month : selfBACK 4.4 (SD 2.5), usual care 5.2 (2.7), |
| Rasmussen et al. (2020) | | population): | mean difference -0.73 (95% CI -1.15 to -0.31), p=0.001. |
| Implementation and analysis protocol | | 3 months: selfBACK 108/209 (52%), usual care 74/190 (39%), OR 1.96, (95% Cl 1.25 to 3.07); between- | p=0.001. |

| Study name and location | Technology name | Functional outcomes | Pain |
|---|---|---|--|
| Rughani et al. (2023) Secondary analysis | | group OR 1.76 (95% CI 1.15 to 2.70) p=0.01 | 9 month : selfBACK 4.0 (SD 2.6), usual care 5.0 (SD 2.8), mean difference -1.00 (95% CI -1.45 to -0.56), |
| Svendsen et al. (2022) Nested qualitative process evaluation | | 9 months: selfBACK 95/170 (56%), usual care 82/182 (45%), OR 2.45 (95%Cl 1.53 to 3.92); between- group OR 1.63 (1.04 to 2.55) | p=NR |
| Sandal et al. (2020) (NCT03697759) | Intervention: selfBACK (PP: 43 | RMDQ (change from BL not tested for significance): | NRS 0-10 (change from BL not tested for significance): |
| Location: Denmark and | patients) | BL (51 patients): Mean 8.6 (SD 5.1) | Average past week: |
| Norway | | 6 weeks (43 patients): Mean 5.9 (SD 4.0) | BL (51 patients): Mean: 4.1 (SD 2.1) 6 weeks (43 patients): Mean: 2.8 (SD 1.8) |
| Associated publications: | | Change score: -1.8 (95% CI: -2.9 to - | Change score: Mean: -1.0 (95% CI: -1.6 to -0.5) |
| NCT03697759 (University of Southern Denmark 2018) CT record | | 0.7) PSFS (change from BL not tested for significance) : BL (51 patients): Mean 3.7 (SD 2.3) 6 weeks (43 patients): Mean 4.7 (SD 2.7) Change score: 1.0 (95% CI: 0.2 to 1.7) | Worst past week: BL (51 patients): Mean: 5.7 (SD 2.1) 6 weeks (43 patients): Mean: 4.6 (SD 2.5) Change score: Mean: -1.0 (95% CI: -1.6 to -0.4) |
| Nordstoga et al. (2020) (Nordstoga et al. 2020) | Intervention: selfBACK | NR | NR |
| Location: Norway and UK | Stage 1 : App version with only physical activity component of the intervention and a web-questionnaire to collect information to tailor self-management plans. | | |

| Study name and location | Technology name | Functional outcomes | Pain |
|--|--|---|---|
| | Stage 2: An app version that incorporated 3 self- management components (physical activity, exercises and education). | | |
| SupportBack | | | |
| Geraghty et al. (2018) Location: UK Geraghty et al. (2015) RCT protocol Geraghty et al. (2020b) post- trial interviews ISRCTN31034004 (University of Southampton 2013) CT record | Arm #1: SupportBack and usual care (30 patients allocated, 25 analysed); Arm #2: SupportBack and physiotherapist support (29 patients allocated, 22 analysed); Arm #3: usual care (28 patients allocated, 26 analysed) | IPAQ: 3 months: SupportBack and usual care median 1130.5 (Q1: 693, Q3:2826), median difference from BL -64.9 (95% CI: -2796.15 to 2666.32); SupportBack and physiotherapist support median 990 (Q1: 396, Q3: 3226.5), median difference from BL - 668.0 (95% CI: -3347.32 to 2011.25); usual care median 2277.5 (Q1: 912, Q3: 6105) RMDQ (73 patients): 3 months: SupportBack and usual care mean 5.8 (SD: 4.5), mean difference from BL -0.7 (95% CI: -2.77 to 1.35); SupportBack and physiotherapist support mean 5.1 (SD: 5.1), mean difference from BL - -1.3 (95% CI: -3.49 to 0.81); usual care mean 6.3 (SD: 5.1) Modified Enablement Scale (58 patients): | Pain intensity (NRS) – index average: 3 month follow-up: Arm #1: mean 3.2(SD: 2.2), mean change from BL -0.8 (95% CI: -1.60 to 0.07); Arm #2: mean 3.1 (SD: 2.0), mean change from BL -0.7 (95% CI: -1.53 to 0.21); Arm #3 mean 3.6 (SD: 2.1). Pain intensity (NRS) – current: 3 month follow-up: Arm #1 mean 3.6 (SD: 2.5), mean change from BL -0.9 (95% CI: -1.86 to 0.16); Arm #2 mean 3.1 (SD: 2.3), mean change from BL -1.4 (95% CI: -2.40 to -0.29); Arm #3 mean 4.0 (SD: 2.5). Pain intensity (NRS) – least pain last 2 weeks: 3 month follow-up: Arm #1 mean 2.3 (SD: 2.3), mean change from BL -0.7 (95% CI: -1.60 to 0.16); Arm #2 mean 2.3 (SD: 2.1), mean change from BL -0.04 (95% CI: -0.97 to 0.89; Arm #3 mean 2.8 (SD: 2.1). Pain intensity (NRS) – average last 2 weeks: 3 month follow-up: Arm #1 mean 3.6 (SD: 2.5), mean change from BL -0.5 (95% CI: -1.56 to 0.54); Arm #2 mean 3.4 (SD: 1.7), mean change from BL -0.9 (95% CI: -1.96 to 0.25; Arm #3 mean 4.1 (SD: 2.1). Days in pain: |
| | | 3 months: SupportBack and usual care mean 25.4 (SD: 9.7), mean difference from BL -2.0 (CI: -8.51 to | 3 month follow-up: Arm #1: median 4 (Q1:0, Q3:15), median difference from BL -0.7 (95% CI: -9.20 to 7.87); Arm #2: median 10 (Q1:3, Q3:20), median |

| Study name and location | Technology name | Functional outcomes | Pain |
|-------------------------|-----------------|--|---|
| | | 4.55); SupportBack and physiotherapist support mean 28.3 (SD: 9.3), mean difference from BL 0.1 (-6.19 to 6.43); usual care mean 27.9 (SD: 10.5) | difference from BL 0.3 (-8.71 to 9.38); Arm #3 median 6 (Q1:2, Q3:20) Differences were not tested for statistical significance. |
| | | STarT Back subgroup for patients receiving SupportBack and usual care: | |
| | | BL: 17 (60.7%) low risk, 8 (28.6%) medium risk, 3 (10.7%) high risk. At 3 month follow-up: 12 (70.6%) low risk, 3 (17.7%) medium risk, 2 (11.8%) high risk. | |
| | | STarT Back subgroup for patients receiving SupportBack and physiotherapist support: | |
| | | BL: 9 (33.3%) low risk, 15 (55.6%) medium risk, 3 (11.1%) high risk. At 3 month follow-up: 14 (73.7%) low risk, 5 (11.8%) medium risk, 0 (0%) high risk. | |
| | | STarT Back subgroup for patients receiving usual care: | |
| | | BL: 15 (51.7%) low risk, 11 (37.9%) medium risk, 3 (10.3%) high risk. At 3 month follow-up: 11 (47.8%) low risk, 10 (43.5%) medium risk, 2 (8.7%) high risk. | |
| | | Differences were not tested for statistical significance. | |

Key: BL – baseline, CI – confidence interval, CT – clinical trial, HFAQ – Hannover functional ability questionnaire, IPAQ – international physical activity questionnaire, ITT – intention-to-treat, LBP – Low back pain, MvK – Modified Von Korff, NR – not reported, NRS – numeric pain rating, PP – per protocol, RMDQ – Roland-Morris disability questionnaire, SD – standard deviation, VAS – visual analogue scale, Vs – Versus.

Table 13.11: 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 |
|---|---|--------------------------------|--------------------------------------|--|--------------------|
| getUBetter | · | | | · | |
| Wanless and McClellan (2019) (Wanless and McClellan 2019) | Intervention: getUBetter | NR | NR | NR | NR |
| Location: UK | | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) | Intervention: getUBetter Comparator: Non-app users | NR | NR | NR | NR |
| Location: UK | | | | | |
| Associated publication: | | | | | |
| Walker et al. (2022) Conference abstract | | | | | |
| Health Innovation Network, Emergency Department Evaluation Report | Intervention: getUBetter | NR | NR | NR | NR |

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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 |
|---|--|--|--------------------------------------|--|--------------------|
| (Health Innovation Network 2022) | | | | | |
| Location: UK | | | | | |
| Hinge | | | | | |
| Shebib et al. (2019) Location: US Associated publications: ISRCTN42338218 (Hinge Health 2017) CT record | Intervention: Hinge in addition to usual care (ITT: 113 patients; PP: 69 patients) Comparator: Three digital education articles in addition to usual care (ITT: 64 patients; PP: 36 patients) | VAS impact on daily life score (ITT): Hinge: BL: Mean 38.6 (SD 26.6) 12 weeks: Mean 21.1 (SD 20.7) Usual care: BL: Mean 43.9 (SD 25.2) 12 weeks: Mean 38.2 (SD 26.1) Mean difference: -11.8 (95% Cl: -19.3, -4.3) p=0.002 VAS impact on daily life score (ITT): | NR | ODI (ITT): Hinge: BL: Mean 21.7 (SD 12.1) 12 weeks: Mean 17.6 (SD 12) Usual care: BL: Mean 21 (SD 9.66) 12 weeks: Mean 21.1 (SD 11.2) Mean difference: -4.1 (95% CI: -6.5, -1.8) p<0.001 | NR |

| 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 |
|---|--|--|--------------------------------------|---|--------------------|
| | | Hinge: BL: Mean 37.3 (SD 28.2) | | Mean difference: -6.9 (95% CI: −10.5, -3.3) p<0.001 | |
| | | 12 weeks: Mean 13.4 (SD14.8) | | ODI 10-point reduction (PP population): Hinge: 19/69 (28%) | |
| | | Usual care: BL: Mean 40.9 (SD 24.7) 12 weeks: Mean 35.3 (SD 27.3) Mean difference: -18.3 (95% Cl: -29, -7.7) p=0.001 | | Usual care: 4/36 (11%) p=0.09 ODI 30% reduction (PP population): Hinge: 38/69 (55%) Usual care: 9/36 (25%) p=0.006 ODI 10 point <i>or</i> 30 point reduction (PP population): Hinge: 40/69 (58%) Usual care: 9/36 (25%) p=0.003 | |
| Bailey et al. (2020) (Bailey et al. 2020) Location: US | Intervention: Hinge | NR | NR | NR | NR |
| Kaia app | 1 | 1 | 1 | 1 | 1 |
| Toelle et al. (2019) Location : Germany | Intervention: Kaia app (PP: 42 patients) | Veterans RAND 12-Item Health Survey Mental Component: | NR | NR | NR |

| 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 |
|-------------------------|--|---|--------------------------------------|--|--------------------|
| | Comparator: Physiotherapy (PP: 44 patients) | BL: Kaia app mean 44.38 (SD 10.08), physiotherapy 44.56 (SD 9.29) p=not significant | | | |
| | | 6 weeks: Kaia app mean 45.53 (SD 7.39), physiotherapy 47.32 (SD 8.25) p=not significant | | | |
| | | 12 weeks: Kaia app mean 48.69 (SD 8.38), physiotherapy 47.64 (SD 8.11) p=not significant | | | |
| | | Veterans RAND 12-Item Health Survey Physical Component: | | | |
| | | BL: Kaia app mean 41.65 (SD 8.00), physiotherapy 40.78 (SD 8.18) p=not significant | | | |

| 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 |
|--|--|---|--------------------------------------|--|--------------------|
| | | 6 weeks: Kaia app mean 46.53 (SD 9.01), physiotherapy 45.56 (SD 8.78) p=not significant | | | |
| | | 12 weeks: Kaia app mean 50.58 (SD 6.86), physiotherapy 48.64 (SD 8.22) p=not significant | | | |
| Priebe et al. (2020a) (Priebe et al. 2020a) | Intervention: Kaia app Comparator: Standard care | NR | NR | NR | NR |
| Location: Germany | | | | | |
| Associated publication: | | | | | |
| DRKS00015048 (Projektzentrale Rise-uP 2018) CT record | | | | | |
| Priebe et al. (2020b) (Priebe et al. 2020b) | Intervention: Kaia app v1 Comparator: Kaia app v2 | NR | NR | NR | NR |

| 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 |
|--|---|--------------------------------|--------------------------------------|--|--------------------|
| Location: Germany | | | | | |
| Jain, 2022 (Jain et al. 2022) | Intervention: Kaia app | NR | NR | NR | NR |
| Location: US | | | | | |
| Clement et al. (2018) (Clement et al. 2018) | Intervention: Kaia app version 0.x and 1.x | NR | NR | NR | NR |
| Location : Austria, Germany Switzerland, UK and US | | | | | |
| Associated publications: Huber et al. (2017) | | | | | |
| Jain et al. (2021) | Intervention : Kaia app | NR | NR | NR | NR |
| Location: International | | | | | |
| selfBACK | | | | | |
| Sandal et al. (2021) (NCT03697759) | Intervention: selfBACK (ITT: 232 patients) | EQ-VAS: 3 months: | NR | NR | NR |

| 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 |
|---|---|--|--------------------------------------|--|--------------------|
| Location: Denmark and Norway Associated publications: Sandal et al. (2019) Protocol NCT03798288 (University of Southern Denmark 2019) CT record Overas et al. (2022) Secondary analysis Rasmussen et al. (2020) Implementation and analysis protocol Rughani et al. (2023) Secondary analysis Svendsen et al. | Comparator: Usual care (ITT: 229 patients) | selfBACK 70.9 (16.9), usual care 70.6 (17.4), Mean difference 0.36 (95% CI -2.42 to - 3.14). 9 months: selfBACK 73.4 (16.1), usual care 71.9 (17.9), mean difference 1.54 (95% CI -1.38 to 4.45). EQ-5D weighted score (range -0.6 to 1.0): 3 months: selfBACK 0.76 (SD 0.12), usual care 0.74 (SD | | | |
| (2022) Nested qualitative process evaluation | | 0.13), mean difference 0.02 (95% CI 0.02 (- 0.01 to 0.04). 9 months: selfBACK 0.78 (SD 0.13), usual | | | |

| 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 |
|---|----------------------------|--|--------------------------------------|--|-----------------------|
| | | care 0.76 (SD 0.14), mean difference 0.02 (95% CI 0.02 (- 0.00 to 0.05). | | | |
| | | P values not reported, authors report that HRQoL scores at 3 months did not differ between groups | | | |
| Sandal et al. (2020) (NCT03697759) Location : Denmark and Norway Associated publications: NCT03697759 (University of Southern Denmark 2018) CT record | Intervention: selfBACK | EuroQol 100mm VAS (change from BL not tested for significance: BL (51 patients): Mean: 65.5 (SD 14.9) 6 weeks (43 patients): Mean: 75.0 (SD 14.7) Change score: Mean: 9.2 (95% Cl: 4.4 to 13.9) | NR | NR | NR |
| Nordstoga et al. (2020) | Intervention: selfBACK: | NR | NR | NR | Stage1: SUS score: |

| 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 |
|-------------------------|---|--------------------------------|--------------------------------------|--|--|
| Location: Norway and UK | Stage 1: App version with only physical activity | | | | Mean SUS score was 64.7 points (SD: 21.2, range 10- 95). |
| | component of the intervention | | | | Patient experience – electronic survey (n=16): |
| | and a web- questionnaire to collect information to tailor self- management plans. Stage 2 : An app version that | | | | 1/3 patients experienced technical difficulties with downloading, installing, or using the app or with synchronizing the wrist-worn activity monitor with their smartphone. 10 (60%) reported step count information as useful, 8 (50%) perceived it as |
| | incorporated 3 self- management components (physical activity, exercises and | | | | accurate. 10 (60%) considered motivational notifications appropriate and 13 (80%) perceived them to be personalised. |
| | education). | | | | Patient experience – telephone interviews (n=10, mean age 51 years, 6 (60%) male): |
| | | | | | Barriers to intervention use included older age, disabilities, older |

| 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 |
|-------------------------|--------------------|--------------------------------|--------------------------------------|--|---|
| | | | | | smartphones, having to continuously carry smartphone for participants struggling to synchronise activity monitor. |
| | | | | | Facilitators included motivational and personalised notifications, daily physical activity and goal achievement reports, selfBACK being recommended by health professionals. |
| | | | | | Stage 2: |
| | | | | | SUS score: |
| | | | | | Mean SUS score 70.5 points (SD: 20.5, range: 45-95). |
| | | | | | Patient experience: |
| | | | | | 5 (50%) found the functions to be well integrated. 2 (20%) found selfBACK to be inconsistent. |
| | | | | | 8 (80%) found physical activity component useful or very useful, 6 (60%) rated education component useful or very useful, 5 (50%) rated |

| 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 |
|--|---|--------------------------------|--------------------------------------|--|--|
| | | | | | information on step count goal useful or very useful. |
| | | | | | 6 (60%) were neutral on whether the app helped manage their LBP, 2 (20%) found it useful, 2 (20%) found it not useful. |
| | | | | | 2 (20%) found weekly tailoring questions asked in the app relevant, 5 (50%) neutral, 3 (30%) not relevant. |
| | | | | | Users thought the information in the educational module was appropriate and the app was easy to use but there were too many technical challenges. |
| SupportBack | | | | | |
| Geraghty et al. (2018) | Arm #1: SupportBack and usual care | NR | NR | NR | NR |
| Location: UK Associated publications: Geraghty et al. (2015) RCT protocol | Arm #2: SupportBack and physiotherapist support; Arm #3: usual care | | | | |

| 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 |
|--|--------------------|--------------------------------|--------------------------------------|--|--------------------|
| Geraghty et al. (2020b) post-trial interviews | | | | | |
| ISRCTN31034004 (University of Southampton 2013) CT record | | | | | |

Key: BIPQ – brief illness perception questionnaire, BL – baseline, CI – confidence interval, CT – clinical trial, EQ-5D – EuroQol, EQ-VAS – EuroQol-visual analogue scale, ITT – intention-to-treat, LBP – Low back pain, NR – not reported, ODI – Oswestry Disability Index 33, PP – per protocol, SD – standard deviation, SUS – system usability scale, VAS – visual analogue scale.

Appendix D – Economic review study selection

Selection of economic studies was performed alongside the selection of clinical studies. Economic evaluations were considered eligible if they reported total costs, effectiveness, incremental analyses or other economic evaluation outcomes, or measured any relevant cost or resource use associated with the use of non-specific LBP for the scoped technologies, including if the studies were in mixed populations. Due to the limited economic evidence, a wider scope was taken with the economic evidence selection when compared with clinical study selection.

2 full text studies were assessed for relevance to economics outcomes and included at full text review. A further 7 costing studies were included, as they partially met the criteria for economic evidence, even if they were not all studies solely focusing on nonspecific LBP.

Appendix E – Deprioritised study characteristics

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments | | |
|--|---|--|--|--|--|--|
| getUBetter | | | | | | |
| Health Innovation Network, Evaluation Report (Health Innovation Network Unpublished) Location : UK Associated publication: Walker 2022 (Walker et al. 2022) Conference abstract | Design: Retrospective cohort GREEN Intervention: getUBetter GREEN Comparator: Non-app users AMBER | Participants: getUBetter: 835 people prescribed getUBetter for LBP (not specified to be non-specific) Jan 2019 – October 2020 Non-app users: NR AMBER Setting: GP practices Place in pathway: NR GREEN | App use Healthcare resource use GREEN | Number of non-app users (and details of care) to whom users were compared is not reported. Study deprioritised due to patient population not fully meeting scope | | |
| Health Innovation Network, Emergency Department Evaluation Report (Health Innovation Network 2022) Location: UK | Design: Retrospective case series and questionnaire GREEN Intervention: getUBetter GREEN Comparator: NA GREEN | Participants: 154 people diagnosed with uncomplicated MSK LBP (included an unspecified number of people with herniation, sciatica and other indications) AMBER Setting: Emergency department (ED) patients (for example, most self-referring to ED, others referred by GP, NHS 111 line, physiotherapist) GREEN | App use Referral rates Clinician satisfaction GREEN | Study deprioritised due to patient population not fully meeting scope | | |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|--|---|---|--|---|
| | | Place in pathway: People referred to app by emergency department clinician GREEN | | |
| Somerset NHS Foundation Trust 2022 (NHS Foundation Trust 2022) Location: UK | Design: Retrospective cohort study GREEN Intervention: getUBetter GREEN Comparator: not referred to getUBetter, but referred to physiotherapy for MSK pain AMBER | Participants: 93 people with LBP (of 384 patients with MSK pain) referred to and registered with the app. LBP not further described.AMBER Acute Vs Chronic LBP: NRSetting: Somerset Foundation Trusts MSK physiotherapy service GREENPlace in pathway: People referred to MSK physiotherapy service (not further described) GREENGREEN | Engagement measures Adverse events | Patient group may not fully meet the scope, as cause of LBP not reported and may include specific causes. Origin of referral to physiotherapy service not reported. Study did not report how many patients in comparator arm had LBP. Study deprioritised due to patient population not fully meeting scope and unclear comparator population. |
| Kaia app | | | | |
| Jain, 2022 (Jain et al. 2022) Location : US | Design: Pilot RCT GREEN Intervention: Kaia app, Kaia Health GREEN | Participants: 40 people with chronic LBP (not specified whether non-specific)Kaia app, Kaia Health: NRLive physical therapy and handouts: NRAMBERAcute Vs Chronic LBP: Chronic | Physiotherapist evaluated acceptability of exercises to demonstrate non- inferiority GREEN | People with LBP (not specified whether non- specific) Study deprioritised due to population not fully meeting the scope |

| Study name and location | Design and intervention(s) | Participants and setting | Outcomes | EAG comments |
|-------------------------|--|---|----------|--------------|
| | Control : Live physical therapy and handouts GREEN | Setting: NR GREEN Place in pathway: NR GREEN | | |

Key: LBP – low back pain, MSK – musculoskeletal, NA – not applicable, NR – not reported; RCT – randomised controlled trial, Vs – Versus.

GREEN: Study characteristic aligns with the scope

AMBER: Study characteristic does not fully align with the scope