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SERVICE EVALUATION

The SelfSTarT intervention for low back pain patients presenting to first contact physiotherapists: A mixed methods service evaluation

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Abstract

Introduction: Globally, back pain is the leading cause of years of disability. In the United Kingdom, over 20 million people live with musculoskeletal (MSK) pain, with low back pain being one of the most common causes. National strategies promote self-management and the use of digital technologies to empower populations.

Aims: To evaluate the uptake and impact of providing the SelfSTart approach (STarT Back and SelfBACK App) when delivered by a First Contact Physiotherapist (FCP) to people presenting with low back pain in primary care.

Methods: Patients presenting with a new episode of low back pain underwent routine assessment and completion of a STarT Back questionnaire. Patients with low/medium scores were offered the SelfBACK App. A control population was provided by the MIDAS-GP study. Patient Experience, outcome measures, healthcare utilisation and retention were captured through the app and clinical systems (EMIS). Interviews with five FCPs explored the experiences of using the SelfSTart approach.

Results: SelfSTarT was taken up by almost half (48%) of those to whom it was offered. Compared to MIDAS-GP, users were more likely to be younger, male, in work, and with higher health literacy. SelfSTarT users reported significant improved experiences relating to receiving an agreed care plan and receiving sufficient information. There were no significant differences in treatments offered. FCPs were positive about the app and felt it had value but wanted feedback on patient progress. They recognised that a digital solution would not be suitable for all.

Conclusion: This approach offers an opportunity to empower and support self-management, using robustly evaluated digital technology.

KEYWORDS
assistive technology, back care, self-management

1 | INTRODUCTION

1.1 | Burden of back pain

Globally, back pain is the leading cause of years of disability (Wu et al., 2020), which creates enormous strain on individuals, healthcare systems and the economy. In the United Kingdom (UK), over 20 million people live with musculoskeletal (MSK) pain, with low back pain being one of the most common causes (Versus Arthritis State of Musculoskeletal Health, 2023). The Major Condition Strategy recently identified musculoskeletal disease as one of the six most impactful conditions for the population, causing 60% of ill health and early death in England (Department of Health, 2023). In the United States, a third of people over 18 report low back pain (Singh et al., 2023). One in three consultations in primary care with a GP is due to an MSK problem (Department of Health, 2006; Keavy, 2020), with back pain being the most common reason people seek primary and emergency care (Casiano et al., 2022). In the USA, in 2013, nearly 62 million visits to hospitals, emergency departments, outpatient clinics, and physician offices included a diagnosis of low back pain (Singh et al., 2023). Inevitably, this impacts people's ability to work, undertake daily tasks and live independently (Versus Arthritis State of the Nation, 2023). For the UK population, it has been recognised that socioeconomic inequities have widened in those presenting to primary care with low back pain (Yu et al., 2023). This means that those living in more deprived areas are more likely to seek help than those in less deprived areas, with primary care in more deprived areas seeing 15%–40% more patients with low back pain (Yu et al., 2023). However, The Kings Fund highlighted that whilst patient numbers grew by 14.5%, the number of GPs only grew by 4.75% and practice nurses by 2.85% (2010–2015). Primary care teams therefore face an increasing demand with a relatively static workforce.

1.2 | FCP workforce

There has been a growing understanding that the increasing age of our population will result in patients with multi-morbidity and more complex needs. More investment in primary care will be required alongside more support for staff development, including 'multi-specialty' models of care consisting of nurses, therapists and community-based professionals (NHS England, 2014). First Contact Practitioners (FCP) were introduced in the UK in 2018, in part, to address these challenges and act as a means of freeing up General Practitioner (GP) capacity. FCPs are generally experienced.

MSK Physiotherapists who have the skills to manage a wide spectrum of MSK disease without the need to see a GP (The Chartered Society of Physiotherapy, 2016). They have the ability to assess and diagnose MSK pain, request imaging and investigations and refer to secondary care. A national evaluation suggests that over two thirds of patients improve following their consultation with an FCP (Stynes et al., 2021). Patients identified satisfaction with FCPs' communication and knowledge, efficiency, treatment provided, assessment skills and service provided in comparison to GP care (Wood et al., 2022). To capture the clinical activity of FCPs working within a large community Trust in the UK (Midlands Partnership University NHS Foundation Trust), an innovative digital system was designed, tested and embedded within the primary care electronic health record system (Egton Medical Information System (EMIS)). FCPs input the patient's condition, the action taken, any referrals made for additional investigations or referrals to secondary care. Since its inception in 2020, it has highlighted that almost a quarter (23%) of all patients seeing an FCP had low back pain (October 2020-1 August 2021).

1.3 | Digital agenda

The UK National Health Service (NHS) vision for the future (The NHS Long Term Plan, 2019) and the Major Conditions Strategy (Department of Health and Social Care, 2023) recognises the significant impact that technology and innovation will have on the way services are planned, delivered and evaluated. Citizens now have access to over 70 approved apps to help support prevention and self-management (The NHS Plan, 2019 and Department of Health and Social Care, 2023). The aspiration is that technology will provide further innovations for clinicians to share best practice, assist in the reduction of red tape, stimulate an enquiring and research culture and support service transformation (The NHS Plan, 2019). For patients, it is envisaged that they will have more control over their care, be able to monitor their healthcare status and have access to their medical records. Some of the day-to-day practical priorities that will help drive digital transformation include: making it easy to access medical care records, use of decision support or predictive tools to support care, making data capture easy and safe, protect privacy and generate linked data sets to gain a better understanding of performance (The NHS Plan, 2019). NHS England prioritised digital innovations in its Programme Funding for 2021 and launched competitive calls to support Integrated Care Systems (ICSs) who had an active interest in introducing or scaling up digital innovations within their MSK pathway. The overall aim is to reduce low clinical value outpatient visits by 30% to digitise, connect and transform care closer to home (NHSx MSK Digital Adoption Fund call). Nine ICSs were supported with a variety of innovative digital ideas ranging from remote health status monitoring to video-based rehabilitation and the use of apps and websites including "getUBetter" and "myrecovery."

1.4 | Self-management

Supported self-management is part of the NHS Long Term Plan's (LTP) commitment to make personalised care the norm. 'Supported self-management' encourages health and care services to support and empower people to manage their ongoing physical and mental health conditions themselves. The vision of the LTP is for everyone in England living with an ongoing health condition or conditions to be empowered to live well with their conditions. More recently, the Major Conditions strategy (Department of Health and Social Care) recognises that in the future, those accessing services will be more complex with more co-morbidity and there will be a greater need to personalise care, empower and support patients, carers, families and communities.

A recent systematic review (Iribarren et al., 2021) explored whether mobile apps had the ability to modify behaviour and promote disease management. The review suggested that apps had the potential to change healthcare behaviour and have a slight advantage over standard care; however, most of the studies identified were undertaken in high income countries and most had a follow-up of 6 months or less. They reported that 156 studies collected continuous health outcome data (involving 21,422 participants). Apps such as GetUbetter have identified an improved ability to self-manage, an improved confidence to self-manage and a better understanding of their condition and recovery. In a pilot conducted in London, 86% of patients would recommend the app to family and friends and 73% felt the app would provide a better GP service (https://transform.england.nhs.uk/key-tools-and-info/digital-playbooks/musculoskeletal-digital-playbook/digital-self-management-and-self-referral-for-musculoskeletal-complaints-in-london/).

1.5 | STarTBack and SelfBACK (evidence-based innovations)

There are two evidence-based primary care innovations that are known to assist in the management of patients with low back pain: the Keele STarT Back risk stratification tool and approach and the SelfBACK App that supports back pain self-management. Both have been rigorously evaluated through randomised controlled trials (Foster et al., 2014; Hill et al., 2011; Sandal et al., 2021).

The STarT Back approach uses the principle of risk-stratification to match patients to suitable treatment options, that is, not all patients with low back pain need the same treatment. It uses a nine-item questionnaire to determine if a patient is at low, medium, or high risk of ongoing persistent disability. Matched treatments are then suggested according to the level of risk. Those at 'low risk' receive good quality self-management information, those at 'medium risk' are referred to physiotherapy, and for those at 'high risk' psychologically informed physiotherapy is recommended. The approach improves clinical outcomes and is cost effective (Foster et al., 2014; Hill et al., 2011), reduces patient disability and days lost from work by half, and results in 30% fewer sickness certificates being issued by primary care doctors. Public Health England identified a return of investment of £224.36 for every £1 spent on using the STarT Back approach (vs. arthritis https://www.versusarthritis.org/research/research-achievements/start-back-targeted-treatment-for-back-pain/) with a conservative estimated annual savings for the UK of £46 million.

SelfBACK is an individually tailored self-management support system that is delivered through an artificial intelligence-based app to support the management of patients with low back pain (Sandal et al., 2021). The approach was tested in a randomised controlled trial which demonstrated the effectiveness of the digital innovation to support patient's self-management by providing information about physical activity, strength and flexibility and daily educational messages (Sandal et al., 2021). Patients using the SelfBACK App were shown to have reduced pain and disability. In a recent study of 461 people with low back pain (Rughani et al., 2023), the SelfBack App was able to improve outcomes for those with high levels of pain and distress. For the purposes of this service evaluation, the combined approach was called **SelfSTarT**.

In summary, the burden of back pain is significant and the opportunity to utilise digital solutions has not been tested by FCPs. This service evaluation aimed to assess the impact on patient and FCPs experience by offering a digital app in primary care in the UK.

Funding was gained through the NHS England Digital Adoption Fund in October 2021. The following discussion with Caldicott Guardians and Information and Governance Managers within the ICS and provider organisations, no ethical approvals were required.

2 | METHODS

2.1 | Governance

This service evaluation did not require ethical approval but in the interests of digital best practice, a Clinical Safety Case Report (CSCR) was compiled, aligning to DCB0160 (NHS Digital, 2018a). NHS Digital "recommend that DCB1029 and DCB0160 are adopted in all circumstances where a digital product is developed or deployed to support health or social care" (NHS Digital, 2018b). At the time of the project, the SelfBACK industry partner did not have its own DCB0129 in place.

2.2 | Patient and public involvement and engagement

Keele University IAU has a strong track record of engaging patients and the public (PPIE) in research (Higginbottom et al., 2017; Hyde et al., 2017), implementation and knowledge mobilisation (Swaithes et al., 2023) activities. PPIE were involved in every stage of the project.

2.2.1 | Increasing FCP and primary care team awareness/clinician training and support

An implementation plan and communication strategy were co-created to facilitate maximum engagement with the key stakeholders, namely primary care teams, GP Practice managers, FCPs, operational and clinical leaders and ICS leaders. The aim, scope and ambition of the project were shared using a variety of media including letters to primary care teams, X (formally known as Twitter), vlogs, blogs, personal communications, presentations to GP Practice meetings, FCP Networks and ICS Boards. Training materials, power point presentations and videos were created to support the FCP in introducing and offering the app to the patient. A new FCP electronic health record template was shared with participating FCP teams that specifically contained a mechanism to invite patients to use SelfBACK (via a digital token) and save a SelfBACK unique ID in their primary care record (to enable data linkage). The implementation plan focused initially on recruiting a small number of FCPs, learning the lessons from that experience, and adapting and supporting the process iteratively. FCPs and primary care teams' participation was voluntary and not incentivised. Core team support was provided to clinicians as needed.

2.3 | What we did- the SelfSTarT intervention

Patients consulting a participating FCP with low back pain were asked to complete a STarT Back risk stratification tool as part of their routine clinical assessment. If the patient was scored at 'low' or 'medium' risk of persistent symptoms on the tool, the patient was eligible to be offered/sign-posted to the SelfBACK App (version 1.4.0) to support their care and was provided with a token during their FCP consultation. Later, in their own time and on their own personal mobile device, patients were able to use the token to access the app free from Google Play or the App Store. During the app registration process, patients were asked to complete a series of questions to enable the app to tailor their self-management messages and exercise programme. Patients continued to receive usual FCP care and their personal engagement with the app was not monitored or discussed further by the clinical team. It is typical for back pain patients who consult an FCP to only attend a single visit, with less than 1% of patients re-visiting their FCP over the next month. The SelfBACK clinician dashboard was not available for use at this time and therefore patients requiring physiotherapy rehabilitation were not able to share their SelfBACK App data with their onward treating physiotherapist.

2.4 | The Keele MIDAS-GP cohort—Used as a comparator/control group

An existing large research programme at Keele University called the MIDAS project (funded by the Nuffield Foundation and vs. Arthritis via the Oliver Bird fund) provided a comparative control sample of primary care low back pain patients. Between September 2021 and June 2022, the MIDAS-GP study recruited a cohort of people with MSK pain, including patients with low back pain ($n = 397$), from GP practices in the same area of North Staffordshire in the UK. In the MIDAS-GP study, clinicians did not have access to the SelfBACK App, and whilst STarT Back is available to GPs in this area, it was not widely used.

The MIDAS-GP cohort was an observational study that captured patient outcomes and experiences within self-report questionnaires with an initial questionnaire completed roughly 2 weeks after the primary care consultation. Patient reported experience measures (PREMs) are detailed in Figure 1. In addition, data from participants' primary care electronic health records were extracted to capture treatment and management decisions over the 6 months following their initial consultation (see Table 3).

2.4.1 | Outcomes for the service evaluation

i. To capture baseline characteristics, patients who downloaded the SelfBACK App were sent an online form 2 weeks after registering that was identical to the MIDAS baseline survey.
ii. Patient experience was measured using the PREM items (Deacon et al., 2021) as the initial questionnaire used in the MIDAS-GP study (see Figure 1).
iii. Similar to the MIDAS-GP study, the medical record data of patients who received the SelfSTarT intervention was extracted and analysed by a member of the NHS clinical team, so that treatment and management decisions could be compared to treatment received by patients in the MIDAS-GP control sample.
iv. The number of patients who declined the app was also captured as well as the app user retention at 1 and 3 months.

2.5 | Nested qualitative study

FCP experiences of the SelfSTarT intervention were explored using a focus group to capture differing views and opinions and identify whether issues raised were single occurrences or widespread experiences. FCPs from services participating in the study were invited to take part on a voluntary basis. The focus group took place in June 2023, was recorded, transcribed verbatim, and analysed through content analysis by HB (a qualitative health services research). The analysis and identified themes were discussed in multidisciplinary study team meetings. As this was part of this service evaluation, ethical approval was not needed.

3 | RESULTS

3.1 | Uptake of the SelfSTarT intervention

For the period of the SelfSTarT evaluation (August 2022 – March 2023), 34 GP practices were actively involved in the evaluation.

- How satisfied were you with the length of time it took to get your first appointment?
  - How good was your health professional at…
    - Involving you as much as you wanted to be in decisions about your care and treatment?
    - Making you feel listened to?
    - Explaining things to you in a way that you could understand?
    - Giving you enough time?
    - Treating you with care and concern?
    -
  - Did you…
    - Have confidence and trust in the health professional you saw or spoke to?
    - Agree or review a care plan with your health professional?
    - Receive sufficient information about your condition or self care that was easy to understand?
    - Feel that your care was well coordinated between health professionals?
    - Feel your needs were met?
    - Receive sufficient guidance on your general health? (physical activity / exercise / smoking / healthy diet / healthy weight / alcohol consumption / mental well being)
  - How convenient have your consultations been?
  - Thinking about your recent appointment with us, overall, how was your experience of our service?
  - If you have any comments, compliments or any areas of the service that you were not happy with then please leave details below.

Deacon et al 2021

FIGURE 1 List of questions within the PREMS.

There were 17 FCPs trained in using the SelfSTarT approach, 13 FCPs were actively engaged in recruiting patients.

There were a total of 3665 FCP appointments available to FCPs participating in the project. There were 2612 appointments episodes that were coded with a 'body part' on the FCP clinical system, of which 473 were coded as low back pain (18%). FCPs recorded, in the medical record, that 129 (27%) patients had been given information about back pain. Of the 473 patients coded with low back pain, 304 (64%) did not have a STarT Back score, 36 (8%) had a high STarT Back score, 89 (19%) had a medium score and 44 (9%) had a low-risk score.

Results from the FCP medical record indicate that 110 (23%) LBP patients were offered the SelfBACK App by their FCP. Of these 110, 88 (80%) accepted the offer of app and 22 (20%) declined. Just under half went onto complete baseline questionnaire form within the app at 2 weeks ($n = 52$) with $n = 28$ completing the PREM questions.

3.2 | Outcomes

(i) Baseline characteristics

Participant baseline characteristics in the SelfSTarT and MIDAS-GP samples can be seen in Table 1. The SelfBACK patients were slightly younger, were more likely to be male and in work rather than retired, and had better levels of health literacy.

(ii) Patient experiences

Patients in the SelfBACK and MIDAS-GP studies reported high levels of satisfaction with their primary care consultation. However, the SelfSTarT sample reported a significantly improved experience for items on (a) receiving sufficient information and (b) having an agreed care plan. Please see Table 2.

(iii) Management of LBP

When comparing low back pain treatment and management decisions, few differences were seen between the SelfSTarT and MIDAS-GP samples (Table 3). For these 81 patients with a STarTBack score, there were no diagnostic requests for 79 patients (98%) two were referred for MRI scans (2%), 26 (30%) were referred to physiotherapy and 55 were not (63%), six were referred for GP review (7%). Please see Table 2.

(iv) App user retention

At 1 month, user retention was 22% and 14% at 3 months.

3.3 | Qualitative experiences of FCPs

Five FCPs took part in the hour-long focus group. Participant characteristics are displayed in Table 4.

Five main themes were identified relating to the adoption and implementation of SelfSTarT. These were *the FCP clinical system, separation of STarT Back and SelfBACK, lack of follow-up and patient*

TABLE 1 Baseline characteristics MIDAS-GP and SelfSTarT.

	MIDAS-GP (control)	SelfSTarT
Total	397	52
Female	285 (72%)	28 (54%)
Age		
Mean (SD)	54.9 (15.9)	51.9 (14.9)
Range	19–91	22–84
White	378 (95%)	28/30 (93%)
BMI		
Mean (SD)	29.3 (6.93)	28.7 (6.4)
Median (IQR)	28.0 (24.3, 33.0)	27.5 (24.3, 32.8)
Poor health literacy		
Always/Often	26 (7%)	1 (2%)
Previous surgery for this problem	53 (13%)	0 (100%)
Duration of current pain episode		
Less than 2 weeks	30 (8)	4 (8%)
2–4 weeks	74 (19)	16 (31%)
5 weeks to 3 months	63 (16)	11 (21%)
>3 months	229 (58)	21 (40%)
Employed (incl. self-employed)	186 (47%)	36 (69%)
Retired	116 (29%)	9 (17%)
Unable to work due to sickness/disability	55 (14%)	0 (0%)
Other		7 (14%)
Pain intensity at baseline		
Mean (SD)	7.2 (2.08)	5.79 (1.61) 6 (5, 7)
Median (IQR)	7 (6, 9)	(n = 35)

digital exclusion, and positive experiences of SelfSTarT. Additional quotes may be seen in the Supplementary Files.

Theme 1 *FCP clinical system (template)*

The first theme identified issues with the FCP clinical system, referred to here as 'the template'. To enable recording of patient consent and study data, and to allow the STarT Back tool to be embedded in the electronic health record system, a system for FCPs to complete in consultations was installed. FCPs reported that using this system was difficult, especially in time-limited consultations:

> The template and timing is probably a big issue. So 20 minute appointment I've got a template to fill out which is clunky and needs improving
>
> (FCP1).

The FCPs reported issues with the template itself, particularly that it hindered writing up of the consultation rather than helping. In some instances, the use of the SelfSTarT FCP template actively discouraged engagement by disrupting the routine write-ups of consultations. The FCPs discussed that they could understand the frustrations with the template, that it works for a research study where detailed data needs to be collected but that this limits its usefulness when implemented into clinical practice:

> The template is a cashing up tool. It's called an FCP template, which I think isn't kind of what it is. It doesn't say what it is on the tin. For me it's a cashing up tool and which is great for data. It's data collection…. yeah it is, but it doesn't help me as a practitioner really.
>
> (FCP3)

The FCPs also discussed that the SelfSTarT process was arduous, time consuming, and therefore a source of frustration:

> But OK, so I've gotta go to the SelfBACK website now, I think this is the problem cause… so I've signed in, I've chosen my service and remember this is all after you've explained what SelfSTarT is and so you've already

TABLE 2 Patient experience of the primary care back pain consultation.

	MIDAS-GP controls (n = 397)	SelfBack (n = 28)
Health professional gives enough time	357 (90%)	24 (86%)
Very/fairly good		
Health professional listens to you	357 (90%)	25 (89%)
Very/fairly good		
Health professional explains tests/treatments	306 (77%)	25 (89%)
Very/fairly good		
Health professional involves you	298 (75%)	25 (89%)
Very/fairly good		
Health professional treats care & concern	347 (88%)	26 (93%)
Very/fairly good		
Agreed a care plan	217 (55%)	25 (89%)
Yes/No		
Received sufficient information	233 (59%)	26 (93%)
Yes/No		
Discussed the impact on work (n = 265)	142 (54%)	
Yes/No		
Needs met	328 (83%)	26 (93%)
Definitely/to some extent		
Convenient appointment	285 (72%)	20 (71%)
Extremely/Very		
Overall experience	323 (81%)	26 (93%)
Very/fairly good		

TABLE 3 Comparison of primary care LBP management options over 6 months from patient's index consultation between SelfSTarT and MIDAS-GP.

	SelfSTarT (n = 88)[†]	MIDAS-GP (n = 397)[†]
LBP management options		
Assessed with STarT back risk tool	-	5 (1)
Referral to physiotherapy	26 (30)	101 (25)
Referral to GP for medication review	6 (7)	-
Refer to GP other	2 (2)	-
Imaging (MRI)	2 (2)	11 (3)
Blood test	0	-
Referred to pain clinic	0	4 (1)
Referred to orthopaedics	0	3 (1)
Referral to social prescribing	0	5 (1)

explained what SelfBACK is and what low, medium and high risk is. And you've explained that 'risk' is a ridiculous word to put in a tool because it panics all the patients. And you've then said, well, you've fit in this low or medium risk, which means you could be for self-management or we could do individualized physio. We've got this wonderful app that can guide you. That's SelfSTarT, do you use a phone et cetera, et cetera. So you've already done all of that. I've come on here, put the telephone number in and confirm that they provided the details… And that's being collected by our partners. Send invitation, close that down or that?

(FCP1)

TABLE 4 FCP characteristics.

Participant	Gender	Years of service as an FCP
FCP1	Male	4 years
FCP2	Female	2 years
FCP3	Female	5 years
FCP4	Female	3 years
FCP5	Male	3 years

Completing this entire process in a time-limited consultation was felt to be too intrusive to clinical practice to be effectively implemented.

Theme 2 *Separating STarT Back and SelfBACK*

FCPs suggested separating STarT Back and SelfBACK for a smoother process, as the processes of the SelfSTarT study purposefully tied the two interventions together. Having SelfBACK as a resource available to be used at the clinicians' judgement was seen as a preferential process:

> Like you say, do you unlink it [Self Back] from STarT Back and just have it as a resource? … So, if it was just there as a resource like Versus Arthritis' back pain exercises, we know that there are gonna be a group of people who are very useful for it going forwards. It could be a really useful generic resource tool for people with back pain.
>
> (FCP1)

This was reinforced by another FCP who highlighted how often they already know whether a patient would be suitable for SelfBACK without needing to do STarT Back:

> I will say that sometimes I think they'd be perfect [for] SelfBACK and I've not even thought about STarT Back yet. I am doing it that way round cause quite often we'll get patients the, you know, they pulled their back two days ago. They're in agony.
>
> (FCP4)

The FCPs discussed different implementation options that might make the process smoother, including a link to the SelfBACK website separately or embedding the process in a new template:

> FCP3: "So from a great perspective, this website could come up on your template. So rather than being in EMIS template, you fill it out, you click the button, it says medium low. Do you want to upload them to SelfBACK? Click on that. So only people that have a login will be able to."
>
> FCP2: "Or it could be embedded in the EMIS template in exactly the same spot, so as soon as it comes up and low medium risk, we could just go ding! and SelfBACK appears."

Theme 3 *Lack of follow-up*

A further barrier to engagement and motivation was the lack of a follow-up with patients once they had been referred to use SelfBACK.

> We don't get feedback cause once we've seen them and sent them on in every way, I'll sort of get them the text and say, well, if you follow the link you can set it up when you get home and then we don't see them again. So I don't, I've had no feedback on it yet.
>
> (FCP4)

As SelfBACK works as a self-management tool, there are no follow-up appointments scheduled to track improvement or progress, leaving the FCPs feeling unsure about the patient acceptability of the intervention or the patients' back pain.

> I think like [FCP4] said there, it's not knowing if the patients are doing it or enjoying it, you haven't got a clue what they're doing.
>
> (FCP5)

It was highlighted that this may be a limitation of the nature of FCP services and that implementing SelfSTarT into primary care has limitations given that it operates differently to secondary care physiotherapy departments.

Theme 4 *Patient digital exclusion*

Patient digital exclusion was an important topic; it was highlighted that some patients do not feel comfortable downloading an app to their personal mobile:

> The sort of main people that don't want to do it is because they don't do phones, they're just not phone savvy. Now, it might be that they use the Internet, but they don't do phone apps. So the fact of having to download an app would terrify them there. I don't wanna go down that route, so if there's any way we can sort of link it to a website and if got like a log in to do on the website, there may be more open to do it. They just don't want to download an app to the phone.
>
> (FCP4)

All FCPs expressed agreement with this, and supported access to SelfBACK via a website as a way to overcome these barriers.

Theme 5 *Positive experiences of SelfSTarT*

Despite the barriers discussed, the FCPs were positive about SelfSTart, and they identified wanting a smoother process to allow them to offer to more patients. Their enthusiasm for SelfSTarT was evident through their active engagement in thinking of ways that SelfSTarT could be improved. It was encouraged for FCPs to use SelfBACK themselves in order to familiarise themselves with it in order to be more informed for patients:

> I think actually playing with the apps quite useful from a patient perspective. I found that quite useful cause when I first came on board on this project, I didn't have a clue what it was to be honest. So is it something, all the FCPs we could give them access from a patient point of view, so that they could educate their patients and be a lot more aware of it.
>
> (FCP5)

Furthermore, there was discussion about the application of SelfSTarT and SelfBACK in other situations, evidencing FCPs belief in the approach, including using SelfSTarT in secondary care physiotherapy:

> …in a Physio department you know how many patients could you potentially manage really well if you did your low risk and your medium risk with an app? We've got so many patients who are on waiting lists. You know, I think that could be something that we could triage people over the phone and send them this app.
>
> (FCP3)

4 | DISCUSSION

4.1 | What were our key findings?

This is the first time that two robustly tested innovations for people with low back pain (STarT Back and SelfBACK) have been linked and evaluated in a clinical pathway. Our work has identified that connecting the two innovations together has shown no significant differences to a clinical pathway compared to one without (MIDAS-GP study). However, we have demonstrated that the SelfBACK App has had a positive impact on patients reporting they have an agreed care plan and that they have received sufficient information. Although there was a high level of retention of the user within 30 days, there was insufficient data to report changes in pain scores compared to the MIDAS-GP population. Those that accepted the offer of digital support were more likely to be male, younger and have a better health literacy score, giving a sense of which populations may be more engaged with this type of offer in the future.

The qualitative evaluation identified that the FCPs felt very positive towards the SelfSTarT approach, despite processes creating additional time pressures for them in the clinic. They identified that the procedures could have been more time efficient and it was important to have patient follow-up data available to them for review. They were also cognisant of a digital offer not being suitable for everyone. This work recognises that if clinicians are required to offer patients an app, we need to consider how we maximise clinician participation by giving them confidence and skills to recruit, helping them understand the benefits to the patient of using the app and ensuring the processes are simple, are not time consuming and has a feedback loop so they can review patient progress if required.

One of the key learning points from the project team concerned the amount of time it took to secure digital/data governance arrangements within the ICS at the start of the project. However, the relationships, collaboration and working with industry partners were seen as significant benefits.

In our initial testing with the PPIE team and web developers, our five patient partners really enjoyed testing and using the app, one describing it as, "a friend in my pocket".

4.2 | Strengths and weaknesses

A key strength of this work was that the two innovations (STarT Back and SelfBACK) were rigorously tested in randomised controlled trials. Many apps/platforms that are currently available have not been through this process of evaluation and as such the team were reassured that there were no major clinical safety concerns.

Another strength of this project was the collaboration from healthcare, academia, industry and patient and public partners. Representation from each sector brought unique skills, expertise and networks to draw upon for guidance. This was especially true for managing the digital and data governance requirements needed at the start of the project.

A successful project management approach was taken to ensure that the evaluation had clear aims and project objectives and individuals had clear roles and responsibilities. The overall deliverables and timeframes were agreed upon and delivered on time. A further strength was being able to link in with an existing research project (MIDAS) to use as a control group. This allowed us to compare pathways without the innovations on offer. Academic colleagues applied for further funding to test out the implementation of the SelfBack App in Saudi Arabia and were successful in gaining funds to explore the clinical barriers and facilitators within the timeframe of the project. Thereby, giving an enhanced understanding of the experience from the FCP perspective.

This service evaluation aimed to implement and link two evidence-based innovations (STarT Back and SelfBACK). The data collection processes linked to this project were identified, by participating FCPs, as clunky and time consuming. Digital innovations need to be integrated into the clinical systems, the clinical consultation and have a quick and simple approach to data collection. This

and the lack of data to report on changes in pain scores is recognised as a clear weakness in this project. In future, linking of the two innovations may be uncoupled to ease the process of offering the SelfBack App to patients.

We recognise the small numbers in the service evaluation and advise caution when interpreting the results. A significant challenge to the project was the time it took to establish the processes required to ensure data governance. ICSs came into effect in July 2022 (https://www.england.nhs.uk/integratedcare/what-is-integrated-care/), and funding for the project was received in October 2021. Consequently, the project was one of the first to test ICS data governance arrangements. As the organisation was in its infancy, this proved to be a time-consuming process. This had a significant impact on the time left to on board patients as it took 12 months to work through the governance processes.

4.3 | How does it link to other digital research?

Marcuzzi et al. (2023) randomised 294 patients with low back and neck pain into three groups. Firstly, SelfBACK and usual care, secondly a web based self-management programme or thirdly usual care. When the primary outcome (MSK HQ, Hill et al., 2016) was measured at 3 months, the app group was not more effective than the other groups. Our work suggests that the FCPs may have highlighted that the digital offer is more acceptable to the younger male population. This may enhance choice for patients during the shared decision-making conversation and reduce the need for onward referral to physiotherapy, if the app is acceptable. This would support better use of limited clinical resources.

Gollish et al. (2019) developed an app to support patients following total hip and knee replacement, with self- management. In keeping with our findings, they reported that patients felt more supported. They were able to demonstrate reduced calls to their service, thereby reducing the clinical burden. They recognised the need for early patient engagement and evaluation strategies when developing such innovations.

Outside MSK, apps have been found to be a useful addition to promote lifestyle change. An app to support weight loss management was tested in a Japanese population (Nakata et al., 2022). A free app, tested in a randomised controlled trial (RCT) with 141 participants has shown a positive impact on weight loss. Of note, this was a free app for participants but only had a 3 month follow-up. All outcomes were self-assessed and participants were encouraged to feedback on adverse events. Participants were incentivised during and after the study to encourage participation. Data input was checked by the study team to ensure participation in the study group. Our evaluation did not have any mechanism to incentivise or prompt participants, nor was any data collected to provide feedback to clinicians.

Government policy and NHS England's vision to see a shift in digital support to guide self-management, treatment and clinical innovation is ambitious. We recognise that many apps/platforms have not been through a robust evaluation such as an RCT. We have identified that for digital offers to work in practice they need to be quick and easy for the practitioners to offer, give patient outcome data in a feedback loop to the clinicians and patients and data governance arrangement need to be clear, simple, responsive and accessible to all.

4.4 | Implications for practice

This service evaluation highlights that digital innovations can be embedded into practice and evaluated; however, supporting processes need to be simple, easy to use and not time consuming. To prepare clinical teams for digital opportunities, consideration should be given to helping staff understand the development and quality of the digital product, its evidence base, its clinical safety and the level of PPIE in its development. Allowing staff to test the digital offer and the on-boarding process before it goes live is highly recommended. The digital offer will not be suitable for all patients but adds to the suite of choices available to patients to support their ongoing self-management. Embedding digital solutions in clinical practice requires a broad range of expertise, including clinicians, clinical safety officers, and patient representatives. Engaging all as early as possible is highly recommended.

5 | CONCLUSION

In summary, this service evaluation illuminated the many factors that need to be considered when offering an app to a patient population. These included the governance and data arrangement that need to be in place, the importance of engaging clinicians in how the app is offered, how to encourage and maintain the retention of the patients to using the app and feedback progress to the clinicians. All of the elements, as well as patient and public engagement in the design of the app, are crucial to supporting the offer going forward. In our work, almost half of the patients who were offered the app accepted the approach. If supported at a policy level, this methodology could support the ambition of supporting self- management and personalising care outcomes via digital innovations that have been tested in a clinical trial and real world setting.

AUTHOR CONTRIBUTIONS

K. Stevenson: Conceptualisation, funding acquisition, methodology, project admin, supervision, writing and reviewing, data curation. **T. Hadley-Barrows**: Methodology, supervising, review and editing. **N. Evans**: Project administration. **L. Campbell**: Project administration, resources. **J. Southam**: Method, review and editing. **A. Chudyk**: Software. **D. Ellington**: Software, data curation. **B. Jeeves**: Software. **C. Jenson**: Data curation software. **S. Kleberg**: software. **H. Birkinshaw**: Methodology, formal analysis. **F. Mair**: Methodology. **K. Dziedzic**: Conceptualisation, supervision. **G. Peat**: Data collation, supervision. **K. P. Jordan**: Data collection, supervision. **D. Yu**: Formal analysis, data supervision. **J. Bailey**: Formal analysis, data collection.

A. Braybooke: Data collection. **C. D. Mallen**: Conceptualisation. **Jonathan C. Hill**: Methodology, supervision, formal analysis, writing and reviewing.

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CONFLICT OF INTEREST STATEMENT

The authors have no conflicts of interest to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Funding was gained through the NHS England Digital Adoption Fund in October 2021. The following discussion with Caldicott Guardians and Information and Governance Managers within the ICS and provider organisations, no ethical approvals were required.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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