CO-CREATING AN APP FOR THE SELF-MANAGEMENT OF PEOPLE LIVING WITH MULTIPLE SCLEROSIS: EVALUATION OF A PILOT

DR PAUL HEPBURN
PROFESSOR ALISON BRETTLE

School of Health & Society Allerton Building,
Frederick Road Campus, University of Salford,
Greater Manchester, M6 6PU / www.salford.ac.uk

ABOUT THE AUTHORS

Paul Hepburn is a Research Fellow at the School of Health and Society.

Alison Brettle is the Director of the Centre for Social and Health Research and Professor of Health Information and Evidence Based Practice at the School of Health and Society.

For further information please contact:

a.brettle@salford.ac.uk

The University of Salford
Allerton Building
The Crescent
Salford
M6 6PU

ACKNOWLEDGEMENTS

We are indebted to staff and patients from the Multiple Sclerosis team at Salford Royal NHS Foundation Trust, in particular Dr David Rog, for their patience, time, and contributions to this report. This work was funded through the Salford Integrated Care Partnership Innovation and Improvement Fund

CONTENTS

Executive summary

EXECUTIVE SUMMARY

There are approximately 430 people with Multiple Sclerosis (MS) living within Salford CCG and over 5550 across Greater Manchester, managed by the Manchester Centre for Clinical Neurosciences (MCCN) MS service. The MS service is growing at a rate of 10% per annum, which is outstripping physical capacity, human capital, and operational resources and the complexity of cases is similarly increasing. Maximising the impact of even less finite "face to face" resource, post SARS Cov-2, by enabling patients and clinicians alike to manage their conditions and caseloads as effectively as possible between appointments, will be critical to the current and future health economy.

The purpose of this project was to customise, deploy and evaluate an App to support the self-management of long-term conditions using Multiple Sclerosis (MS) as a case exemplar. The App in question was a mature, CE-marked product. The project was conceived as a co-creation project working with people with multiple sclerosis (PwMS), Health Care Professionals (HCPs) and other stakeholders to customise an App to the satisfaction of its intended users. The customised App was to be deployed as a pilot project to a minimum of 50 and maximum of 150 PwMS for a period of 6 months. The project was funded by Salford Clinical Commissioning Group (CCG).

The project successfully integrated patient requirements into the design of the App. This process involved, in a series of workshops: 10 MS patients, the consultant neurologist leading the study team from SRFT; representative from the MS Trust; a representative from the technology partner; and the MS patient representative on the study team. The latter's participation was particularly productive as he, spontaneously, agreed with the other MS patients to establish a facebook group for the MS patients to continue discussing the App outside of the planned co-creation process. This was a facility that proved invaluable at this stage in that it served as a 'back channel' process that delivered more insight from the patients on required design specifications for the App.

The evaluation was a mixed methods study that was largely, but not exclusively, summative in nature where evidence was collected from both quantitative and qualitative data. The quantitative data was sourced from: (i) a questionnaire sent to the App users (PwMS) to gauge their levels of self-efficacy at the start and end of their use of the App and (ii) the Apps on-board metrics that were collected and analysed to demonstrate the pattern of usage by PwMS. More qualitative data was collected from conducting focus groups with patients, all of which were conducted remotely. However, the extraordinary challenges of the Covid pandemic forced the project design to switch from face-face to wholly digital, this impacted upon patient recruitment and retention and, necessarily, the results. In this context the qualitative data has assumed greater importance than was originally envisaged.

The project succeeded in recruiting 52 patients to use the App, achieving its minimum target of 50 users. Ongoing engagement and retention of these patients with the App proved challenging and 25 patients went onto to use the App and of these only 1 used it for 6 months. Again, this was largely, but not exclusively, a function of the Covid constrained environment within which project staff and patients were working.

The low number of users produced insufficient quantitative data from onboard metrics or self-efficacy questionnaires to draw meaningful findings about the App's usage and impact on patient self-efficacy. A series of focus groups which involved 13 patients and 2 HCPs were successful in providing qualitative data that has furnished the project with the following learning points.

LEARNING POINTS

1 It is important to inculcate a culture that convinces the staff responsible for delivering the project, and the wider MS clinical Team, of the merits of the endeavour.

2 Submitting an appropriate and timely NHS ethics application is challenging but crucial. It is well known that researchers should build in appropriate time to navigate NHS ethics, however navigating ethics and governance at both local and national levels immediately post covid proved challenging and time consuming which impacted adversely on the project's timeline and the time remaining to recruit patients.

3 **It is important to develop and sustain a patient advisory group (PAG). This is seen as fundamental to the success of similar projects. Whilst the patient representation on this project management board worked well a broader PAG should have been established and supported.**

4 The project should be appropriately resourced. In this instance lack of such resources was largely a function of the Covid constraints but this impacted adversely on the project. The first was for patient recruitment where the staff at Salford Royal often appeared overwhelmed and the second was the lack of a single dedicated project manager for the length of the project.

5 Appropriate digital avenues for recruiting patients should be fully exploited. For example, use of a QR code that patients could scan to enable them to access the App and appropriate supporting documentation, has worked in similar projects.

6 Digital recruitment methods could well exclude those lacking in digital confidence so should be used in conjunction with specific, targeted methods to ensure the inclusion of the socio-economically disadvantaged or digitally illiterate in any such project. One example might be using local meeting spaces, libraries etc, to host an introductory session to the purpose of the App.

7 Trusted relationships are essential for patient recruitment. This might involve for example, using the MS nurses to build upon their relationships with patients or, as an HCP suggested, exploiting the doctor – patient relationship and foreground the consultants in recruitment literature or videos.

8 Patient onboarding to the App needs to be thought through carefully to ensure understanding of the benefits and engagement with the App. The marketing industry contend that a 'good' onboarding can result in up to a 50% increase in user retention for the App in question. Testimony from participants suggested that the onboarding process did not achieve this and potentially explained the low or infrequent usage of the App. Greater resources and attention should be applied to this stage in any future iteration of the project and where possible should be via face-to-face interactive group sessions. These sessions should not only instruct patient on how to use the device but should emphasise the benefits to the patient from using the App.

9 Notifications are common to most Apps and patients appeared surprised that this feature was absent from this App. There is evidence that such 'push factors' can promote greater patient engagement with the device in question.

10 It is important to reduce 'participant burden'. Evidence suggests this can increase patient retention. Features of the digital tool used here failed to do this. Firstly, the device was not an App. It was a web link that could be accessed from a mobile device, but it was not designed specifically for this purpose. As such many of the participants used their laptops instead with some suggesting they might have used it more if it had been an App on their phone. Another recurring theme from the patient interviews was that the App's questions were repetitive. Patients perceived that they were being asked the same question but in a slightly different way.

11 The device should provide real time data on patient usage to enable staff to contact patients and provide support if required.

12 A consistent set of staff working on the project will facilitate communication and project delivery as intended. Here, staff changed throughout the project both at SRFT and at the technology partner which hampered communication and product delivery.

13 The technology partner should be mandated to produce a beta version of the App that can be used by study staff and patients alike to identify and rectify any issues. A development environment version of the App was sufficiently different to be able to draw any conclusions on live format and usability. The technology partner were unable to provide iterations of the App, based upon feedback through the study, as had been envisaged.

14 Individualisation of an App is, according to the marketing industry, 'craved by App users.' This was underlined here by several participants who commented that the App's features were less appropriate to PwMS who had been living with MS for a while, but whose illness was relatively stable. Alongside this another mentioned that given dexterity was an issue for PwMS the App should have the facility to receive oral instruction through an interface.

15 The device should enable the rating, by PwMS, of the bespoke meta-tagged information (from the MS Trust), pushed to the PwMS based upon their initial digital profile of symptoms and other MS-related characteristics.

16 Utilising the above learning points should lead to optimum usage as it is more likely that patient engagement and retention with the digital device would be increased. However, evidence collected here suggests that patients would still use the device as frequently as it suited them and their circumstances. When asked about how often they would use such a device – when fully customised and integrated into their patient record at the hospital- the responses varied from 'daily' to 'once every month or two.' So the lesson here is that as long as this is satisfactory for the patient and their clinical care, and they do remain engaged with the device, then their frequency of use may be less significant.

1.

INTRODUCTION

The capability of digital Apps in a healthcare context is a tantalising prospect that, in theory, can help deliver a more cost-effective healthcare service (Baltaxe 2019, Gopal 2019, Haase, 2018). In practice this has proved harder to achieve largely due to the difficulties in overcoming two, interlinked challenges namely: achieving an effective adoption and diffusion of the technology and the obdurate nature and structure of the existing health economy (Asthana et al, 2019, Huckman, 2018; Henderson et al, 2013). This project primarily addresses the first challenge with a view to moving onto the second.

The purpose of this project was to customise, deploy and evaluate an App to support the self-management of long-term conditions using Multiple Sclerosis (MS) as a case exemplar. The project was conceived as a co-creation project working with people with multiple sclerosis (PwMS), clinicians and other stakeholders to customise an App to the satisfaction of its intended users. The customised App was to be deployed as a pilot project to a maximum of 150 PwMS for a period of 6 months.

The App in question is a mature, CE-marked product, and was a generic health self-management tool produced by the technology partner and was one of the top-rated NHS Apps on the NHS endorsed ORCHA App review platform. The App allowed for patient self-monitoring and education, can be customised for particular conditions and enabled remote monitoring by MS health professionals. Monitoring includes built in measures that are patient reported outcome measures (PROMs) or patient reported experience measures (PREMs) including quality of life, pain and fatigue. The App had the ability to launch information provided by third parties (in this case the MS Trust); these could be matched by the App's algorithms to give patients the information they need depending upon, type or stage of disease and symptoms and /or disabilities, as well as to demographics such as education, gender, reading age, language etc. The App had features that support the collection and sharing of information between people living with MS and the health professionals with whom they interact.

This case study was initiated and managed by a partnership between the NHS, the third sector, industry, academia and an MS patient representative, namely: Salford Royal Foundation Trust Hospital (SFRT); the MS Trust; the technology partner; and the University of Salford. The patient representative was a longstanding champion for people with MS in the Greater Manchester region and a patient of the MS clinic at SRFT. The case study was financed by an innovation grant from Salford CCG.

Prior research in this area has demonstrated a general value of digital information provision in the self-management of long-term conditions. Focus groups conducted by UoS and SRFT Hospital, among MS patients and clinicians of Salford Royal, provided evidence of a need and desire for digital tools to help in the self-management of MS specifically. However, there remains a dearth of empirical data to support the widespread deployment of such e-health provision (see literature review at Appendix 1) and SARs-COV2 has lent such innovation a new urgency. Indeed, recent research (Leigh, 2021) has pointed to a significant increase, since the onset of the SARs-COV2 pandemic, in interest in digital health products amongst the general population. It is in this context that this study has contributed evidence.

However, this project was conceived, designed, and funded pre- pandemic. Consequently, methods and timelines were revised, and findings impacted. Nonetheless, valuable lessons for future research that seek to maximise the online opportunities afforded by digital technologies have been learnt and will be documented as part of this evaluation.

2.
BACKGROUND

Our project is at the heart of the NHS long term plan (2019), specifically in its focus upon delivering world class care for major health problems, assisting people to age well and the imperative to adopt digital technologies to transform the health of the UK population. The Department of Health has identified that the number of people with long-term conditions and multi-morbidities are rising, in part due to an aging population. Enabling individuals' capacity to self-manage their health is key to reducing the healthcare burden from long term conditions. The SARS Cov-2 pandemic has necessitated a step-change in working practices and behaviours of the NHS and in expectations of patients alike.

For example,

1 Most outpatient services have reverted to telephone or video consultations.

2 Organisations have identified the consequent opportunities for estate cost savings and therefore are unlikely to revert back fully to face to face consultations.

3 Directly commissioned (specialist) services have been effectively moved onto emergency block contracts from payment by results tariffs and NHS England have stated that this has accelerated necessary change in this regard.

4 SARS Cov-2 has also had a devastating effect upon the income and therefore function of the voluntary sector.

The time is ripe for consolidating both these advantages and addressing these financial challenges, to enable longer-term sustainability (Greenhalgh et al, 2017) of quality services for those with long-term conditions, even with finite resources, through leveraging digital enablers and a wider collaboration of NHS, academic, industry and 3rd voluntary sector partners. Maximising the impact of even less finite "face to face" resource, post SARS Cov-2, by enabling patients and clinicians alike to manage their conditions and caseloads as effectively as possible **between appointments**, will be crucial. We fully recognise that any digital solution will not immediately solve all of these issues, but there is a pressing need to begin to deploy and evaluate Apps as part of an ongoing process that will enable more patients with long-term conditions to self-manage, through provision of appropriate educational materials, over the years ahead.

Our project was informed by a series of preliminary focus groups (3 focus groups: 2 x MS patients with different grades of disability and 1 x MS health professionals) that we conducted and supplemented with semi-structured interviews with over 40 MS patients in MS outpatient clinics at Salford Royal Hospital. Alongside establishing a real appetite for using a digital App, this process also provided a long list of requirements that stakeholders felt would be useful in helping patients and clinicians to manage the patient's condition efficiently and effectively between clinical appointments.

This includes, for example:

- Improving patient control over their data and data use – such as: a digital diary for recording pattern of illness, or, accessing information about what is 'normal' health for their age, for example, they want to be able to attribute poor health/sleeplessness/cognitive impairment to MS condition or not; the results of blood tests; provision of information on other support services, for example, social services, citizens advice, wheelchair services, benefits etc.

- The ability to manage relationships between health care professionals and people living with MS, such as: receiving information about a patient before they arrive for their appointment, or, giving patients access to the right kind of professional at the right time, ability to foster personal/trusted relationships and enhance the sense that they are being 'looked after' and supported, timely reassurance/advice regarding efficacy of new medicines or latest 'miracle' cure.

2.1 Multiple Sclerosis in Salford

Specifically, in relation to our project, there are approximately 430 people with Multiple Sclerosis (MS) living within Salford Clinical Commissioning Group (CCG) and around 5550 across Greater Manchester, managed by the Manchester Centre for Clinical Neurosciences (MCCN) MS service. The MS service is growing at a rate of 10% per annum, which is outstripping physical capacity, human capital, and operational resources and the complexity of cases is similarly increasing. MS is an ideal long-term condition to choose as an exemplar of digitally enabled self-management, because:

- MS has a broad range of symptoms and features, and many are common to other long-term conditions, including; fatigue, co-morbid depression and anxiety, physical and cognitive deficits, which can present both acutely and worsen progressively.

- MS most commonly presents between the ages of 20-40 years, which matches that of digitally native technology users better than many other common long-term conditions that have a later onset.

- The most avid users of health Apps in general are young females which also matches the demographic of MS incidence (3:1 female).

- Within the MS population there is a cohort of highly motivated patients and we have already involved many of these in project scoping focus groups, which together with clinicians, have identified an overwhelming need and desire for digital tools to help in the self-management of MS specifically. The MCCN MS team have developed their levels of digital maturity in clinical practice since 2014 and this project is a logical next step in development.

- The MS team already provide trusted 3rd sector patient education information to patients from the MS Trust in paper-based format. Research acknowledges that effective provision of information is a determinant in helping people self-manage their own illness (Astin et al, 2008) which then has the potential to improve self-care, health behaviour, and quality of life (Coulter and Ellis, 2008; Davis, 2010).

Self-management for chronically ill patients is highly suggested and even required, especially for patients who see their specialist occasionally and need to manage their condition daily (Wagner et al., 2001). Self-management has been shown to play a role in the reduction of disease exacerbations in chronically sick patients and improve adherence to rehabilitation (Bodenheimer, 2002; Gallagher et al., 2008; Duscha et al., 2018). However, more evidence is needed regarding which components of self-management are effective (Panagiota et al, 2014). Patient self-efficacy is highly correlated with patient self-management (Strecher et al., 1986; Sarkar et al., 2006; Ross and Mirowsky, 2010; Bethancourt et al., 2014). It has also been shown to improve self-management, in direct and indirect ways, in studies where participants have made statistically significant improvements in their health status, self-efficacy and health behaviours and had fewer emergency department visits (Lorig et al., 2001; Lauren et al., 2016). It is patient self -efficacy that will be gauged here by utilising the Generalised Self Efficacy scale (Schwarzer, R., & Jerusalem, M. 1995).

However, we still know little on the role of digital technology on MS patients' self-efficacy of health-related activities and on if/how chronically ill patients use and experience the widely available technology and indeed, the clinical benefits associated with such technology (Wang et al., 2014; Hamine et al., 2015; McCabe et al., 2017; Marziniak et al, 2018). Smith and Magnani (2019) usefully urge caution in applying digital technologies as they carry the additional challenge of digital health literacy, which demands particular skills complementary to general and health literacy. Populations at risk for limited health literacy are similarly vulnerable to having challenges with digital health literacy.

As such the project was keen to understand and describe the particular challenges faced by the digitally illiterate. Whilst there are a number of explanatory variables for the lack of digital skills within the wider population the ONS (2019) have also shown a clear link between poverty and digital exclusion: just over 1 in 2 (52%) low-income households do not have an internet connection. Given that Salford, our catchment area for this research, is amongst the 20% most deprived local authority areas in England (IMD, 2019) we were concerned to address this by giving several digital tablets to those we assessed were in need and had access to someone, a carer/ friend/ family member, who could help train them in using the device. It was expected that an evaluation of this group of users would reveal some of the barriers to their digital inclusion.

3.

AIMS OF THE PROJECT

This study will examine the principle of digital self-management, alongside the acceptability and use of the App.

Primary Objective:

To investigate acceptability and use of the App in the context of MS

Also striking a note of caution is Jongen et al (2020) who, concluding a 4-month study of the effect of digital technology on PwMS, counselled against expecting a short-term improvement in empowerment in terms of self-efficacy, self-management, autonomy, or participation in first time users of the technology.

Secondary Objectives:

1 Use co-creation methods to customise the App for PwMS.

2 Recruit 2 cohorts of patients with MS to use the App – the general population and those who fall into the bracket of the socio-economically disadvantaged. Educate these groups in the use of the App as necessary (online, using Microsoft Teams), and collect baseline self-efficacy data.

3 Measure acceptability and use of the MS App in both cohorts at the end of the evaluation period.

4 Detect change in self efficacy measures at 3 points in time; beginning (baseline), midpoint, and end of the evaluation period.

5 Explore the ability of the App in meeting the information and support needs of MS patients, through use of meta-tagged data from the MS Trust.

6 Explore the use of the App in improving service delivery from a patient and staff perspective.

7 Identify the challenges associated with providing access to the technology to a socio-economically disadvantaged group.

8 Identify learnings that can be translated into future service needs and other long-term conditions and self-management and create a toolkit to describe these.

3.1 The Project design

This project was designed to run for 12 months and progressed through three stages: the first 3 months focused on customising and deploying the App; the next 6 months involved trialling the App with between 50 and 150 users; with the final 3 months expended on evaluating and documenting the pattern of usage.

It is worth noting here that ethics approval had to be obtained from both the NHS and the University of Salford prior to commencing the project. These ethics submissions are important documents for two reasons (i) without ethics approval the project could not have proceeded and (ii) the content of the submission constrains the project's design for the duration the project, as such, when it became apparent that aspects of the project design where not working, for example with regard to patient recruitment, alternative approaches were precluded by the ethics submission.

The process of submitting and gaining approval for the NHS Ethics took considerably longer than anticipated and impacted upon the project timeline. This was partly due to a lack of clarity from the Ethics committee and HRA regarding whether notification to the MHRA was required if we were using the App beyond its originally notified approved use.

4.

CO-PRODUCING THE PROJECT

This case study was conceived as a co-creation project with PwMS, clinicians and other partners collaborating to customise, deploy and evaluate the App and each of these stages will be discussed in more depth below.

Scholarship on co-creation/co-production in the healthcare context has highlighted the benefits to the quality of care that patients receive (see for example: Elg et al 2012; Leone et al, 2012; Vasilica et al 2020). However, whilst co-creation and co-production are often used interchangeably there appear to be as many definitions as there are scholarly articles. Fortunately Brandsen and Honingh (2018,) have divined shared commonalities: a) they constitute a part of the production process of services, (b) they refer to collaboration between professional service providers and citizens/users, and that (c) active input by citizens is needed to shape the service. The importance of including both professional staff and patients in this process was underlined by recent studies (Greenhalgh et al, 2018; Maguire et al, 2018) and indeed the former suggested that acceptance by professional staff may be the single most important determinant of whether a new technology-supported service succeeds or fails at a local level.

The co-creation of public services is not a new idea. Indeed, it is almost three decades since Elinor Ostrom (Ostrom et al, 1978) put forward the simple, yet foundational idea, that citizens might not only participate in consuming public services but in producing them as well. However, it is interesting to note that while this idea has been part of the public sector reform agenda for some time now (Department of Health,2010; Department of Health and Social Care, 2020) it is still one that is, more often than not, practised at the margins of mainstream public service delivery. One reason for this is the evidence base for the impact of co-production within this domain remains thin (Durose et al, 2014; Vennick et al 2015; Robert et al, 2020) and this is a problem. Part of the problem here is that the identified benefits flowing from co-production processes are largely relational in nature (Durose et al, 2014) and while such social connections can be usefully quantified and graphically illustrated, by for example, social network analysis, a sense of the meaning and value of this process for the participants, both service users and providers, can only be captured through more qualitative analysis - one that captures their stories or narratives. It is these methods that have largely been marginalised within a dominant culture that has viewed public services as a product to be delivered, as a transactional process between providers and consumers that can be accounted for in solely numerical terms.

This is unfortunate as evidence from interviews with service users suggest the process has increased their levels of social capital (Hatzidimitriadou, E, 2012; Bartnik, E, 2007; Seyfang, 2004) This is not an insignificant benefit both for the wider context for local public service delivery and the specific context of this evaluation where improved patient self-efficacy is seen as an important outcome for their healthcare. Nonetheless this is not an argument for promoting one form of evidence over another. Quantitative measures are clearly useful in registering a range of effective service outcomes and will be key in our evaluation here.

But rather it is an argument for conceptualising co-production as a systemic feature of the public service delivery process as opposed to viewing it as an ‘add- on’ to the existing system. Whilst lessons can be learned from this evaluation that will enable some of the benefits to be gained as part of a larger roll-out of this scheme, the wider relational benefits – and as such the overall effectiveness of the service - are unlikely to be secured unless co-production is placed at the heart of the service delivery process.

Co-production also implies partnership between professional providers of public services and clients (Farr, 2018) as such the partnership established to initiate and conduct the study was integral to the project.

With representation from patients, clinicians, academia, industry and the third sector this was seen as a broad, dynamic partnership where knowledge and 'know-how' could be combined in an inter and transdisciplinary framework to drive sustainable innovation and adoption. Moreover, this was considered fundamental to achieving our stated objectives in the context of a health and social care landscape characterized by fragmentation and isolated clusters that, commentators have argued (Asthana, 2019; Albury, 2018; Long 2013;), is the major obstacle to the adoption and diffusion of technological innovation. The patient representative proved particularly important in upholding the concept of co-creation and partnership ensuring, through a social media forum for PwMS established by the representative to run in parallel but independently of the project, that patient voices were ever present in the decision-making process.

5.

CUSTOMISING THE APP

The App is a CE marked medical device and is a mature, generic health self-management tool and our purpose here was to customise the App to meet the objective of this study, namely: to enable people with MS to self-manage their condition.

To this end we deployed a co-creation process involving people living with MS, along with representatives of the study partnership, to collaborate in re-specifying the App as appropriate.

Accordingly, our process involved 10 MS patients from Salford Royal's MS clinic and the consultant neurologist leading the study team from SRFT. Also involved were a researcher from the UoS (as an observer); a representative from the MS Trust; and, the MS patient representative on the study team. The latter's participation was particularly productive as he, spontaneously, agreed with the other MS patients to establish a Facebook group[1] for the MS patients to continue discussing the App outside of the planned co-creation process. This was a facility that proved invaluable at this stage in that it served as a 'back channel' process that delivered more insight from the patients on required design specifications for the App.

The 10 MS patients were self-selected[2] and, along with the other stakeholders listed above, joined in one of four online 'workshops' where all participants were 'walked through' the design and functionality of the App. This was facilitated by the technology partner responsible for the App. These 'walk-throughs' lasted from between 1- 2hours and introduced each aspect of the App to the participants who were encouraged throughout the session to comment on the design and function for ease of use and suitability for their condition. After observing the first workshop UoS research staff suggested the format be altered to allow for more patient interaction and this was duly accepted by the technology partner.

Following this, these ‘walk-through’ sessions of the App were characterised by a productive dialogue between all participants but particularly between the clinical staff representative and the patients: patients suggested design alterations to better suit their condition and what they felt was more likely to sustain their use of the App; whilst the clinician promoted changes that might prove beneficial to the time he spent with the patient in clinic. Across the four sessions this dialogue was effective in producing a long list, 31 in total, of design specifications.

Time and budget were a clear constraint on the fulfilment of this list. To address this all participants were asked to prioritise each suggested specification by allocating a score of between 1 (nice but not necessary) and 10 (absolutely necessary). It was here that the facebook group established by the MS patient representative proved particularly useful as the MS patients were able to discuss the strengths and weaknesses of each specification within their own forum and without any mediation. The scores were then aggregated but the patients’ rankings were provided separately. This was done to ensure that the MS patients’ priorities, the users of the App, were given precedence. This ranked list was then passed to the technology partner who assessed if each specification was within the scope of the agreed contract and its development time. This process produced a final list of 16 design specifications all of which had scored between 4.8 and 10 on the patients’ rankings (see Appendix 2).

An additional design feature of the App tailored to meet the specific self-management needs of the MS patients was the information to be provided by the MS Trust. To recap, this attribute of the App is designed to launch information, provided by the MS Trust, to a user via an algorithm within the App that will match information with the user’s particular stage of the disease, level of disability, age, education and gender. In other words, the patients’ digital profile should trigger appropriate literature for their information. It was anticipated that this service would assist the App user in providing information to enable them to self-manage their condition (Astin et al, 2008.)

To select the information content the MS Trust chose the top 50 most accessed articles on their website. This list was then passed on for discussion, and approved, in the facebook group established by the MS patient representative. Once approved each piece of content was meta-tagged by the MS Trust and then passed onto the technology partner to specify an algorithm to ensure that each user received content appropriate to their specific requirements. This is an important provision as Wulfovich et al (2019) have shown that the potential for improving self-management can depend on the perceived experience and the App’s appropriateness to the patient’s context and needs.

6.

METHOD

6.1 Evaluation approach

The approach adopted here was largely, but not exclusively, summative in nature and comprised a mixed methods design where evidence was collected from both quantitative and qualitative data. The quantitative data was sourced from: (i) a questionnaire sent to the App users (PwMS) to gauge their levels of self-efficacy at the start and end of their use of the App and (ii) the Apps on-board metrics that were collected and analysed to demonstrate the pattern of usage by PwMS.

More qualitative data was collected from focus groups all of which were conducted remotely. The initial aim was to separate the participants into groups by age, disease progression and levels of digital literacy. It was anticipated this latter group would consist of those who had requested a digital device. A further group would comprise those health care professionals who had participated directly or indirectly in the project.

However, an analysis of the App’s metrics (see below) and the fact that no digital devices were requested precluded this approach. The App’s metrics revealed a lower-than-expected number of users of the App, 25 out of a possible 52. An attempt was made to divide groups between frequent, not so frequent, and non-users (these were patients who had ‘signed up’ to use the App but never actually used it). In practice the distinction between frequent and not so frequent users was not observed as a few participants failed to make the interview they had been allocated and ended up joining a different group.

There was no response from any non-users. Individual interviews were conducted with the relevant Health Care Professionals. In total 13 patients and 2 HCPs participated in the qualitative data collection process.

These focus groups were all conducted pseudonymously, in other words the researcher did not have access to any of the participants' personal details and the online sessions were managed by the MS team at SRFT. The group interviews were semi-structured. The recordings of these sessions were transcribed and then analysed to foreground emerging themes. Analyses from both sets of data were then integrated to inform a whole view of how participants used the App. It should be emphasised that our evaluation is situated within a narrative driven methodology that deploys views of users of the App and those of relevant HCPs to illuminate how such digital devices may be effectively used to benefit patient care.

The UoS research team, who conducted this evaluation, also participated in the Project Management Team. In doing so we provided advice and commentary, influencing and shaping aspects of the project as it evolved, this had elements of a more formative evaluation.

6.1 Recruitment of PwMS

The MS team at Salford Royal (consisting of MS neurologist, MS nurses, research nurses and research practitioners), were solely responsible for identifying potential participants.

6.2 Sample

All patients with MS who lived in Salford and attended the MS Clinic at SRFT were eligible for participation in the study. These numbered 430. The project aimed to recruit between 50 and 150 participants to use the App for 6 months These patients were identified using the PAS system by the MS Team. These were then filtered through the project's agreed criteria for inclusion in, and conversely exclusion from, the project:

6.3 Inclusion Criteria:

- Patients aged 18 year or older.

- Residents of Salford Clinical Commissioning Group and / or those registered with a Salford CCG GP and those included in the original scoping focus groups.

- Patients with a diagnosis of multiple sclerosis made according to contemporary diagnostic criteria.

- Can converse in English.

- Able to provide informed consent to the study.

6.4 Exclusion Criteria:

- Patients under 18 years of age.

- Residents of Salford Clinical Commissioning Group and / or those registered with a Salford CCG GP and those included in the original scoping focus groups.

- Patients with a diagnosis of multiple sclerosis made according to contemporary diagnostic criteria.

- Can converse in English.

- Able to provide informed consent to the study.

Once a final list had been collated it was subjected to a clinical review by the MS Nurses and MS Consultants, which resulted in a final list of 250 patients to invite to participate in the study. These patients were then contacted for consent to proceed.

6.5 Recruitment procedure

In practice the process for recruiting and onboarding PwMS deviated from its initial conception and a number of valuable lessons were learnt that are documented later in the report.

The initial conception was to recruit participants, face-to-face, from the MS clinic at Salford Royal this was revised once research resumed under Covid restrictions. Instead, once the final patient sample had been identified, they were sent via post: an information pack containing an invitation to join the study; a Patient Information Sheet (PIS); and a consent form (ICF) (Appendix 3). In practice this proved painfully slow. Packs went missing in the internal post and patients that did receive them many chose not to respond and as such this process elicited a very low response rate. This was only improved by members of the SRFT MS Team delivering the information pack by hand and then contacting- and this included using the Consultant Neurologist managing the project - by telephone, each patient on the list to explain the study, and take consent if interested.

This consent process also proved laborious: it was either granted over the telephone and the MS team member signed the consent form on the patient's behalf and posted a copy of the form back to the patient. Or the patient signed the consent form and posted it back to the MS Team at SRFT.

Figure 1 illustrates this laborious rate of consenting over a period of 6 months with just under two fifths (21) of the total number (52) consenting towards the end of the project in January.

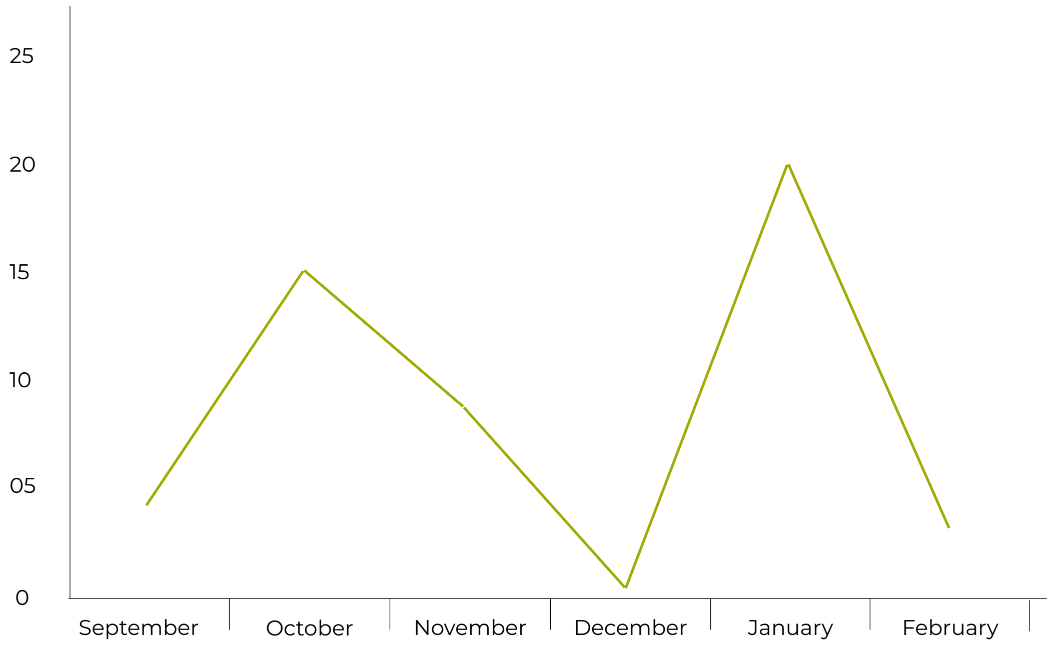
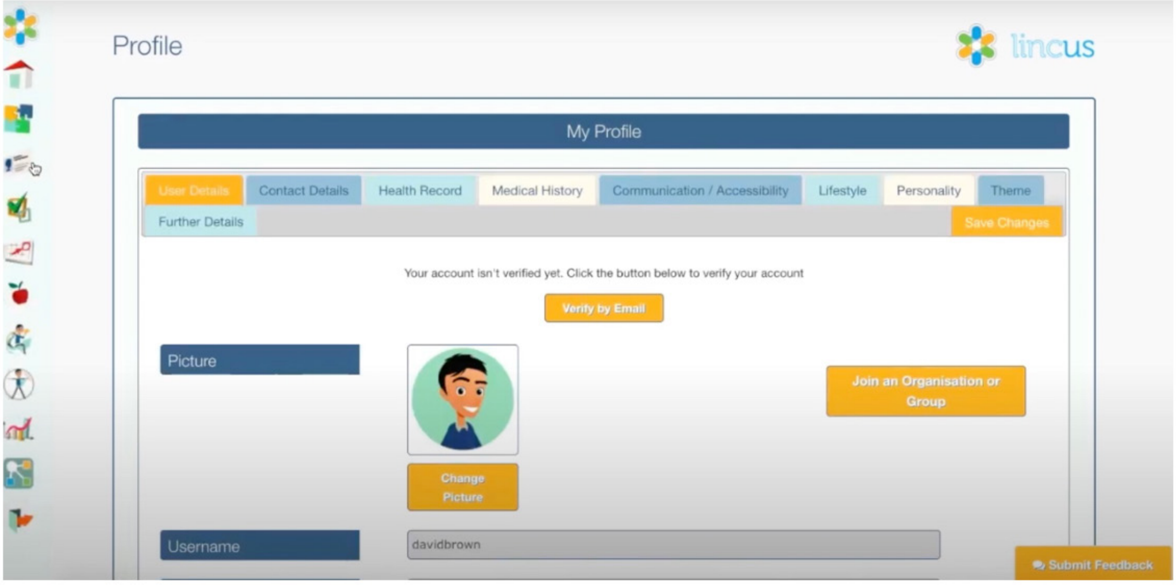


Figure 1. Number of patients consenting between Sept 2021 and February 2022

7.

ONBOARDING

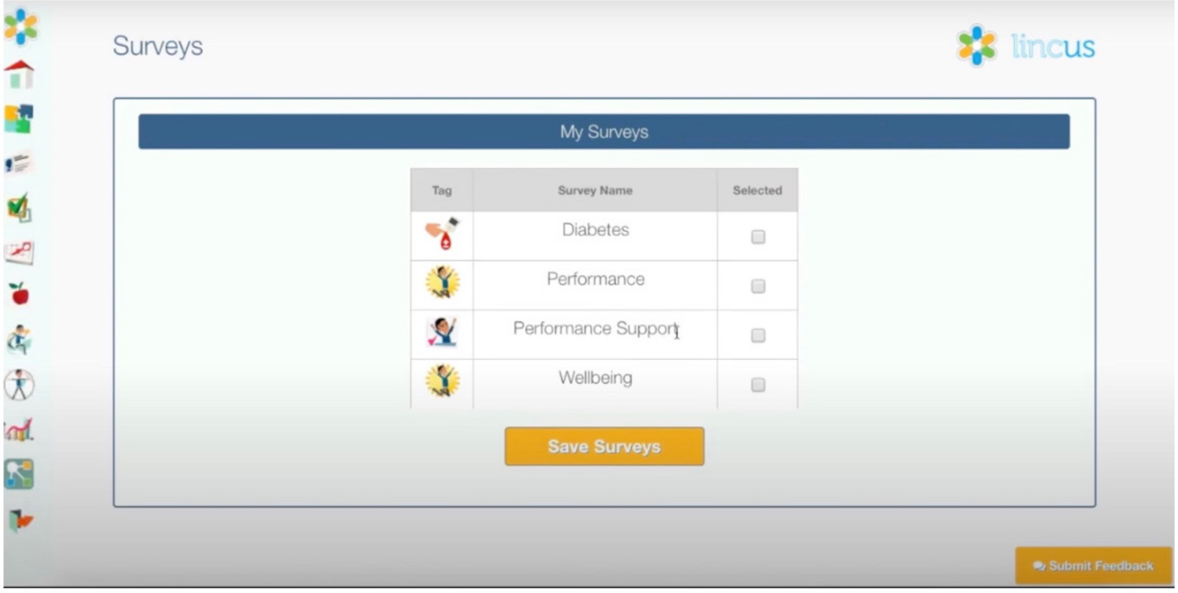
Once consent had been given the patient was ‘onboarded’ by the MS team, during this telephone call, onto the App. The participant was informed how to access the App (as a weblink) the necessary steps to take to start using the App, that is complete a digital profile (see screenshot 1) and set up their surveys (see screenshots 2 and 3) and events (screenshot 4). Surveys and events were designed to provide a record of the users’ physical and mental health over time. So, for example, a wellbeing survey would enable the user to record how energetic or alert they felt on a particular day. They could also record a complementary event, a social visit for example, that may help to explain how they felt that day. If required, the MS team member would talk the participant through each of these stages.



Your account isn't verified yet. Click the button below to verify your account

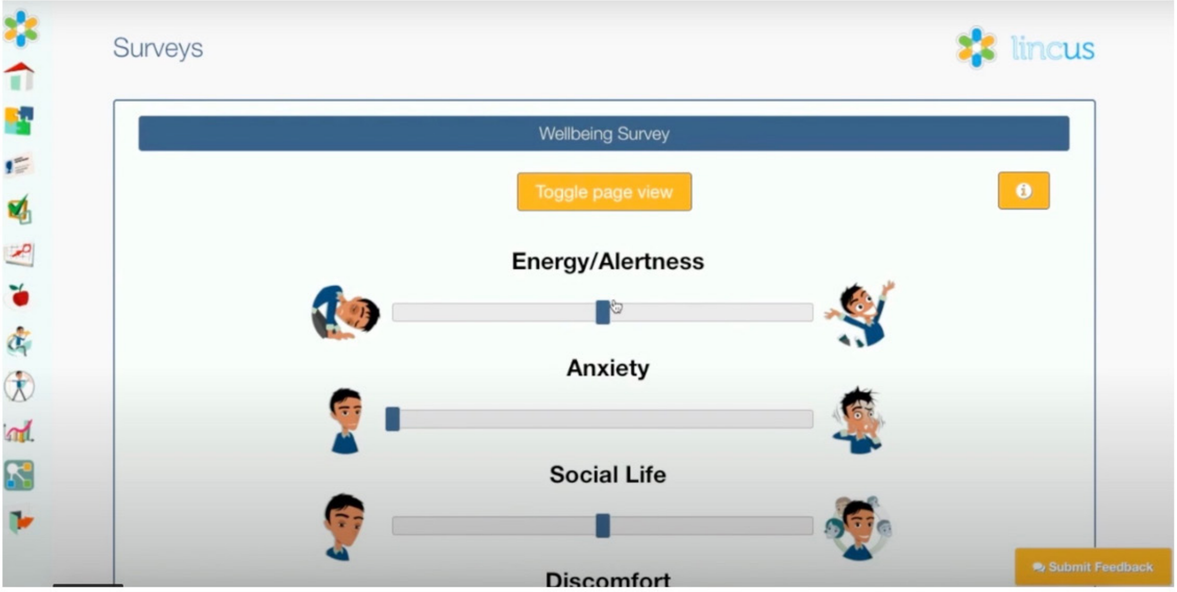
Username: davidbrown

Screenshot 1: Participant’s digital profile on the App

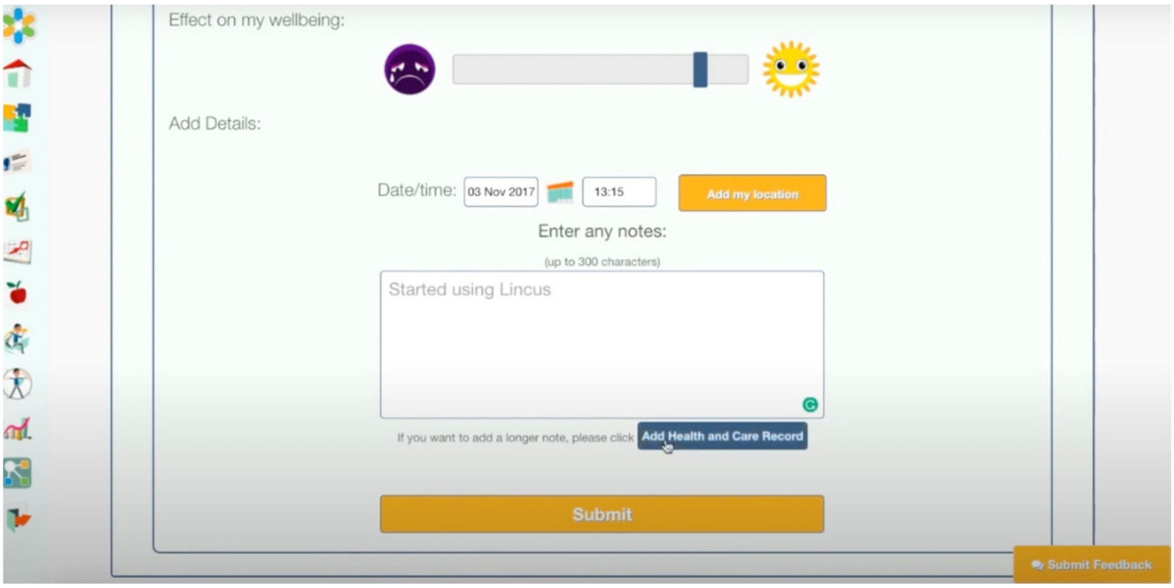


Tag	Survey Name	Selected
	Diabetes	☐
	Performance	☐
	Performance Support	☐
	Wellbeing	☐

Screenshot 2: Choice of the App’s surveys



Screenshot 3: A wellbeing survey



Date/time: 03 Nov 2017 13:15

Started using Lincus

Screenshot 4: An event

This onboarding session was supplemented by access to a series of short webcasts, hosted on youtube:

[(https://youtube.com/playlist?list=PLVICKrhUOQAmFJUX0MVEgSyzrOMrK1dYk).](https://youtube.com/playlist?list=PLVICKrhUOQAmFJUX0MVEgSyzrOMrK1dYk)

Once the Digital Profile was completed the participant could begin to use the App. At the same time a unique user ID was created for the participant which enabled the Research team to analyse and compare individual usage pseudonymously. At the end of this onboarding process the MS team member was also required to introduce, and conduct on the participant's behalf, the online self-efficacy questionnaire (see Appendix 4).

It should be noted here that in accordance with the project's aim to assess the particular challenges of engaging with digitally disadvantaged patients a total of 14 tablets were made available for use by those deemed eligible. Accordingly, when initial contact was made with the patient they were asked if they had access to suitable device from which to use the App. If they did not and they: (i) lived in the most socio-economically deprived part of Salford as defined by the Government's Index of Multiple Deprivation https://www.gov.uk/government/statistics/english-indices-of-deprivation-2019; and (ii) had a carer/relative/friend within their covid-bubble who would be able to help work the device then they would be provided with one of the tablets. It is also worth emphasising here that the devices must come equipped with internet connectivity given the likelihood of a lack of such connectivity in low-income households (ONS, 2019).

Over a 6-month period the project recruited 52 participants to use the App. No digital devices were requested. The expectation here was that PwMS would, for the first 2 weeks, complete the surveys on a daily basis to gain an understanding in the variations of symptoms.

8.

EVALUATION FINDINGS

8.1 Self-efficacy

The Generalised Self-Efficacy (GSE) scale (Schwarzer, R., & Jerusalem, M. 1995) was administered via an online questionnaire (see Appendix 4) to a total of 44 patients prior to them using the App and then once again at the end of the project. The questionnaire contained a unique user ID and 10 tick box questions asking the respondent to acknowledge if a statement was 'not at all true'; 'hardly true'; 'moderately true'; or 'exactly true'. Each response was given a score of 1,2,3, or 4 respectively. The scores for each respondent were then summed giving a maximum of 40, indicating a high degree of self-efficacy, or a minimum of 10 suggesting a low degree of self-efficacy.

Of the 44 completing the baseline questionnaire only 33 completed the endpoint one and of these only 18 had used the App. The following Table 1 details the results of the GSE score for these 18 users. The App usage column in the table corresponds with the usage categories in ***Figure 3*** so, high, mid, and low usage captures those who used it for more than 4 months, between 1 and 4 months and under a month respectively.

These results show a fall, between the baseline and endpoint measure, not only in the average but also largely in the individual GSE score. However, it should be noted that the participants' baseline scores indicated a high self-efficacy suggesting that the project attracted those patients who were already highly motivated.

8.2 Data from the onboard metrics

As ***Figure 2*** illustrates a total of 52 participants had agreed to use the App but analysis of the onboard metrics revealed that 32 logged in and only 25 of these had used it to complete any surveys or events. It is these users this analysis will focus on.

Figure 3 demonstrates 15 had used it for more than a month and, of these, 7 had gone on to use it for more than 4 months. As the figure also shows the majority of users were female who comprised 72% of all users (18). However, males were more likely to use the App for a longer period with over half of them (4) using it for more than 4 months compared to a sixth of females. The only indication of frequency of use by these users is provided by the number of logins each user made and this is shown in Figure 4. This reveals that of the 7 who had used the App for longest the average logon rate was once every 11 days. However, 2 were logging in most frequently at a rate of once every 4 or 5 days. It is, perhaps indicative, that a third of users stopped using the App after 7 days.

The App's 'surveys' proved to be more popular than its 'events' with all users completing 259 of the former, compared to 108 of the latter. The breakdown of these surveys and events can be seen in figures 5 and 6 respectively. 'General Health' and 'Health and Wellbeing' were the most completed survey and event. In terms of gender use only 2 males completed events.

User IDs	Baseline GSE Score	Endpoint GSE Score	App usage
17632	31	30	high
17677	39	18	
17697	29	23	
17718	39	34	
17724	30	32	
17659	31	35	
17706	40	8	mid
17730	40	24	
17781	30	28	
17641	32	36	
17629	37	34	
17631	32	33	low
17638	40	21	
17752	31	31	
17662	31	21	
17703	29	28	
17778	30	26	
17826	36	31	
			20
Average GSE	34	27	

Table 1: Comparison of baseline and endpoint GSE score for those who used the App and completed both GSE questionnaires

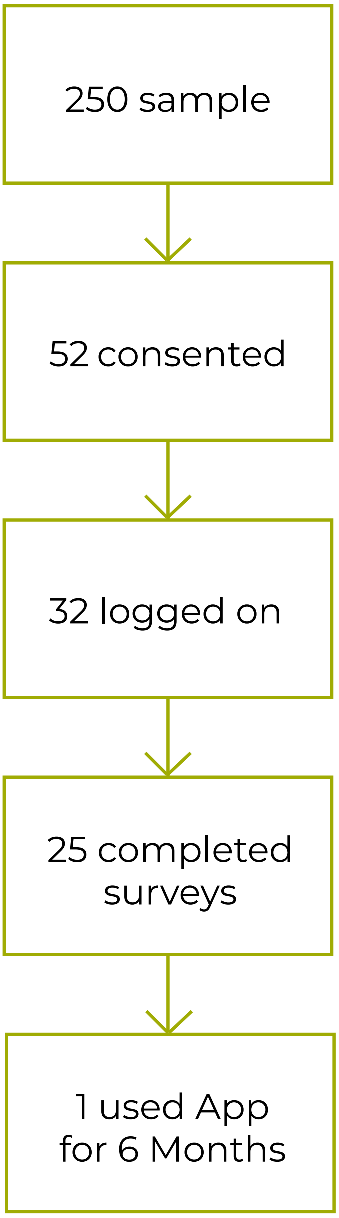


Figure 2 : Patient recruitment and retention flow chart

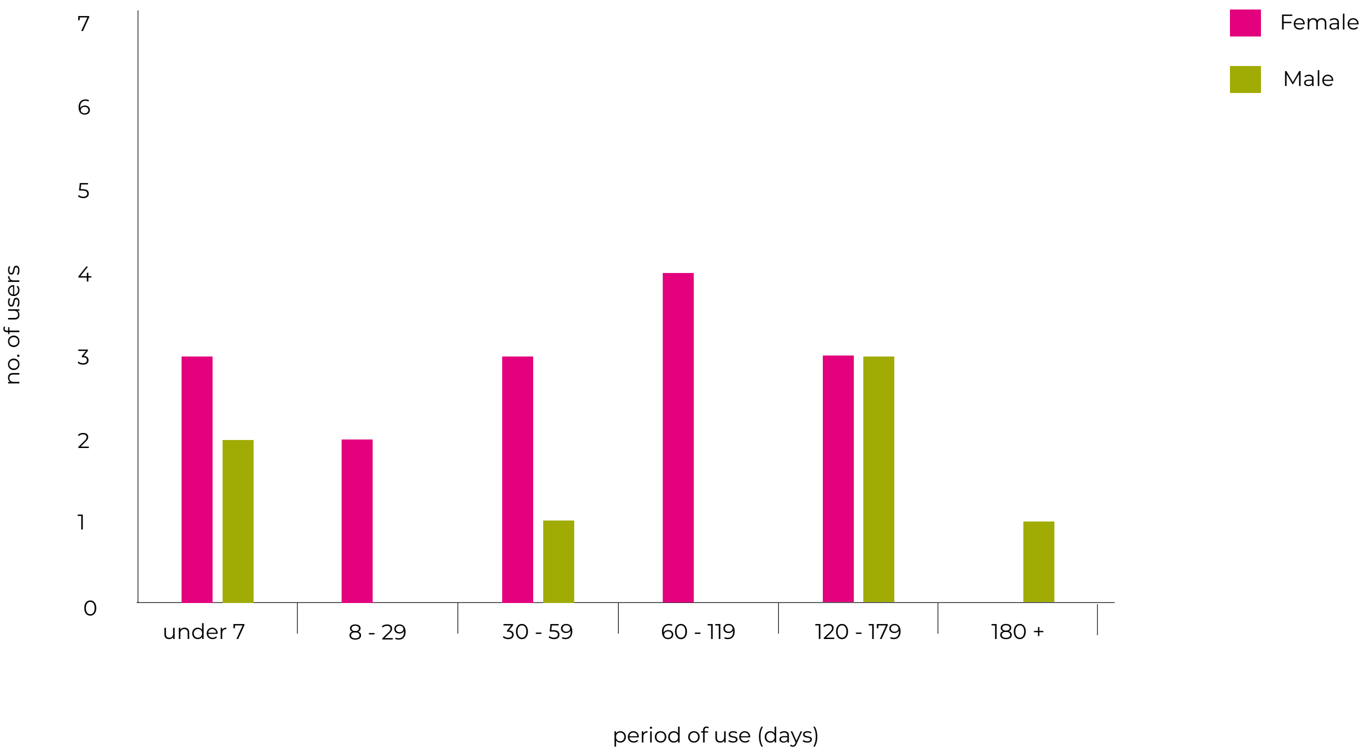


Figure 3: Number of users (n = 25) completing surveys or events by period of days they used the App and by gender

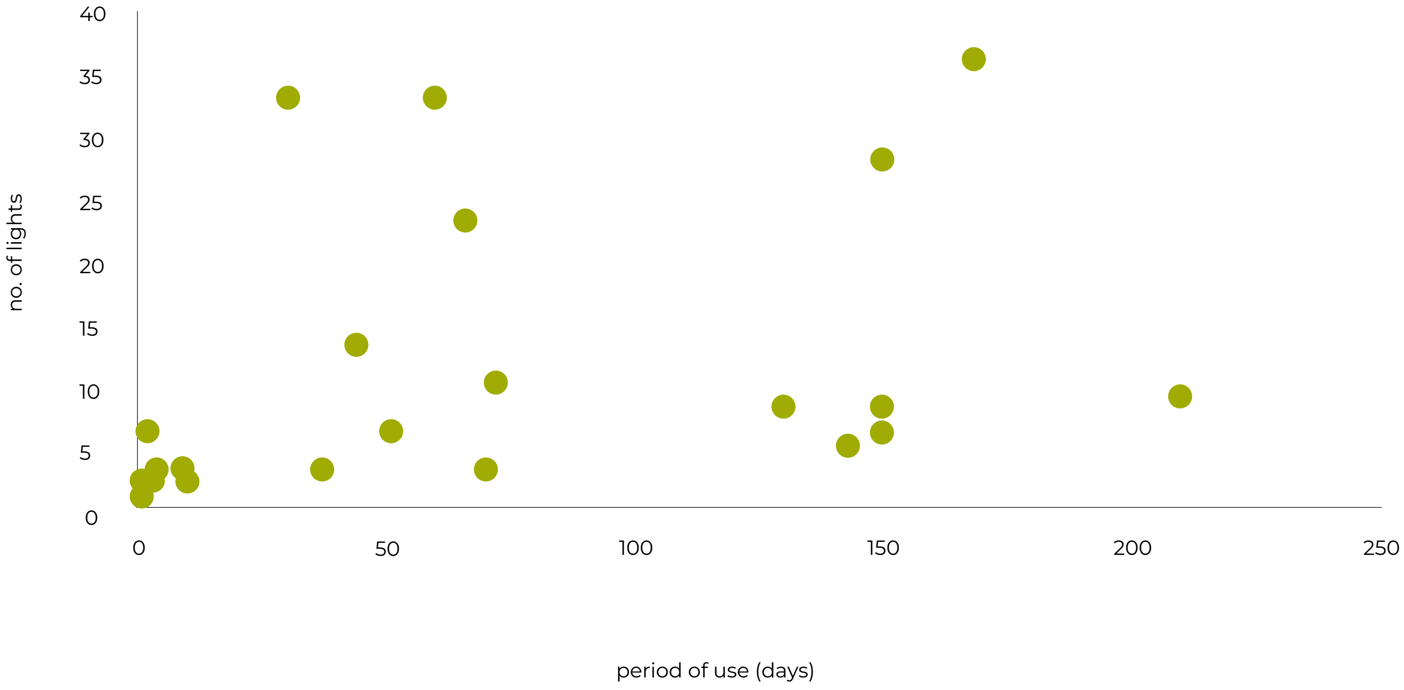


Figure 4: number of logins by each user (25) over period of days

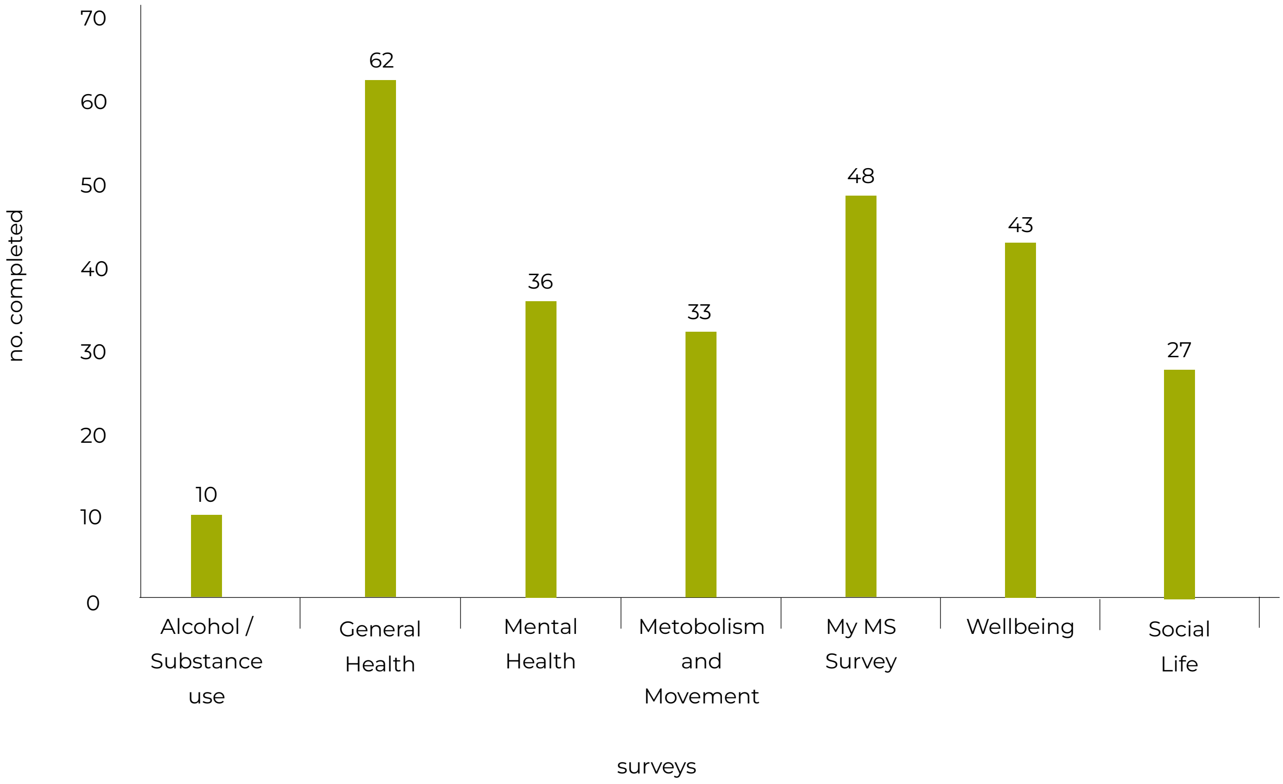


Figure 5: Breakdown of surveys completed (259 in total)

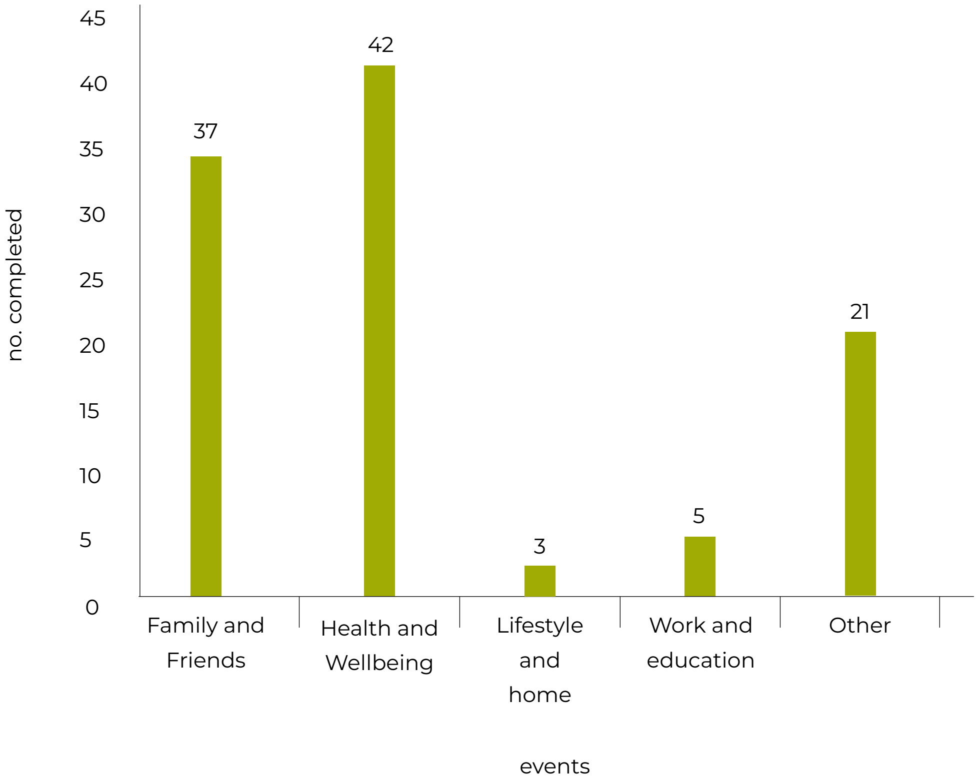


Figure 6: Breakdown of events completed (108 in total)

8.4 Focus groups

Of the 25 patients who had used the App, 13 participated in five focus groups interviews. There were: two groups of four people; one group of two people; and three individual interviews. A further two individual interviews was conducted with the Health Care Professionals (HCPs) who had helped manage patient engagement with the project. All interviews were recorded, transcribed, and then thematically analysed using NVivo software.

Emergent themes from the patient interviews include: patient onboarding; usability; library content; and optimum usage. These will be discussed in turn below. Following these, the issue of engaging patients with the App will be explored drawing upon the interviews with the HCPs.

8.41 Patient interviews

8.42 Patient onboarding

Introducing participants to the App, explaining how it works, what is expected from the participant and why their involvement is important are all factors that the marketing industry[3]consider critical to maintaining engagement with the digital device[4]. Indeed, the industry contend that a 'good' onboarding can result in up to a 50% increase in user retention for the App in question.

The following quotations from the interviews conducted with patients suggest that the onboarding process conducted here needs to be revisited.

I thought - see, I may have misconstrued what it was. I was thinking it was more a case of finding how me, i.e., any patient, how you feel day to day. I've got good days, a bad day, I'm going - I'm thinking now about people, you guys who use the information - I'm thinking, how useful is this for you lot? What are you gaining from it, from me? That's the way that I took it. I might be totally wrong, but that's the way that I took it. FG1 240322

The main thing I've used on there is the surveys. I had a look around the rest of it, and I'm not really sure what I'm doing, what the other stuff is, because there's a thing to log events on there. I was like, well, what events do I log? I'm not just going to report my life on there, and then when I add and look at logging about nutrition and exercise on there, I'm not going to log every meal and every time I do exercise, how that was, on there. So yes, I don't really get what I should be doing there. FG3 280322-3

Yes. I'm not sure it was explained to me very well - but I might be wrong, though. That could just be me. I've not used it every day; I don't know if that was the intention? FG2 280322

I think it needs streamlining a little bit, especially the questionnaire, the survey. I think we need to know what is - I mean, I know the idea is to fill it in, but if you said fill it in once a week, then I'd think right I will put it in once a week. I don't know whether any of us know what the recommended thing is. Do we only fill it in when we have symptoms, or do it once a month? You see, I just thought it was too onerous, and I thought I was expected to fill it in every day, and I just found that - in fact, it was a little bit stressful. FG3 280322-2

I don't know that I've used it properly. I've used it enough to give you that sort of answer. The questionnaires is pretty well the limit of my usage on it. I'm not sure what else is there FG3 280322-4

I liked that one, because I concentrate on the well-being things, but underneath there's a few things that I've never even looked, but doesn't seem, I don't know what to do with it. It says, 'Add events,' but what events to do you add? FG4 310322 4

Yes, that's a big one. What is an event? FG4 310322 3

Right, why would that be beneficial to the information in this app? FG4 310322 3

...I found, I don't know if it's because I'm not a tech-savvy person because I'm dead old-fashioned, I try to do something like, do your diary, like your weight management, any exercises. I've put it in, but I felt like I wasn't putting it in. I don't know if that makes sense to you. I did find it a little bit confusing. I wasn't quite sure what I've got to do. How I've got to do it and then when I did put any information in, I wasn't sure where I've actually put it. FG4 310322

I think I'm a bit like {name} I liked the app ... and I think at certain points in time it will be really useful, but at the time that I was filling it in, it didn't necessarily - because there wasn't an issue with my mood it didn't seem to be relevant. So having spent time ... chart and all that kind of thing, that, having something, a chart for other people to look at, is tedious at the best of times. I wasn't convinced that anybody would look at it if I spent all this time recording what I was eating and things. I'm trying to eat healthily, so I didn't record it every day for somebody else to say, 'Oh, yes, that's fine.' FG3 280322-1

These quotations come from four out of the five groups interviewed, comprising 11 participants, where the issues with onboarding were spontaneously raised by the patients. This suggests that patients were confused about the purpose of the App and its functions, and this may have contributed to the low uptake and use.

8.43 Usability

Usability of a digital device is generally captured as a series of metrics designed to assess how easy and effective the device was for users. Such metrics can be qualitative or quantitative in nature but here we are using patients' oral testimonies to indicate levels of effectiveness, efficiency, and user satisfaction with the App. These testimonies highlighted a range of issues that effected the usability of the App for the patients participating in this project. Firstly, it should be emphasised that there were some positive experiences, and in general, as these patients explain, the App's features were easily navigable:

Yes, I found it easy. There is some really good stuff on there, when you go into the different sections, like life and stuff like that. So I found it easy. I do think it is a good app for - I might not use it all the time, but there might be something on there at a certain point that will benefit, and things like that. I can see, for me, I think it worked well at certain times, certain points. FG3 280322-2

Yes, in terms of ease of use, I thought it was fairly straightforward. You'd login to the welcome page and it would show you other bits which you could login there. So, I found that all right. FG3 280322-3

Surprisingly, given that they were not as well used as the surveys, it was the diet and activity events on the App that were specifically cited as useful.

I mainly used the modules for well-being, but when I had a personal conversation with the consultant three weeks ago, it was; it's quite useful to go through the well-being modules to see how I was feeling at the time, over the period. That was useful, and at the moment I'm finding it useful to look at my diet. My exercise is very limited at the minute! There are things I can envisage - it's prompting me for things I could improve, yes. The diet: I have started eating more fruit since I did it, and drinking more water; I think they've been a bit of a prompt there. So I suppose, yes, that may be the most useful one, perhaps. FG2 280322

Well, I must admit I did it probably for one of the two weeks, because to get a - and I did the diet, the exercise, where I was going, and everything like that. So I did that, which it is good to look back on, but I think logging it every day was quite hard FG3 280322-2

I liked that I could put down events. I liked that the nutrition and the exercise was there, because I'm not very active at the moment, but I intend to be! If I get to that point where I am, then I can just log in what I've done and... FG1 240322-2:

8.43a Needs to be an App!

There was, however, a negative issue with the fact that although the service could be accessed via a participant's mobile phone, this was not an 'App' that could be downloaded from the App store and installed onto a mobile phone but was simply a 'url' connected to the customised the App's website. As such usage was not as simple as clicking on the numerous Apps that patients in our sample regularly used on their mobile phones. The patients' comments, below, point to the need for an App designed to be accessed from a mobile phone. This was also emphasised by the HCPs who were interviewed. Indeed, the implication here is that usage may have increased if it had been accessible as an App.

Plus, I was expecting an app, like I could go on my Apple phone and download the app. The way I access the surveys is to go, my original email that I got, that said, 'Gave them my username and password.' That's how I get into the app, and is that right? Is that what most people do? FG4 310322 4

I think for me it was the fact that there was no app button, because I'd forget - we always forget, and the home page could be less busy. The tabs on the top were very small. They could be made bigger at the home page, and the information that's on the home page, like your events, information, the library access - that could be on a different page. There was a lot of repetition through the - from the website. You press on one link - you'd get taken to something that's pretty similar. It just needs neatening up a little bit and making things a bit more visible rather than having to keep scrolling! FG1 240322-2

Yes, I've probably used it about four, five, six times a month. I think it would be more useful if I'd joined up my mobile device because then I could just... Rather than getting a laptop out, I could just click on an app - on the link, basically. So that would've been quicker, but because I'm using a laptop I find it a bit time-consuming because I've got to get the thing out and make sure it's charged up and all the usual things. I don't have it on all the time. FG2 280322

8.43b Stage of illness

Patient testimony here suggests that the App's usefulness may be contingent upon the patient's stage of illness with MS. The proposition is that the App would be more useful for someone newly diagnosed or suffering a relapse in their condition. The App's functionality would serve a useful purpose in permitting such a patient to mitigate their anxiety by enabling them to record and track their heath whilst furnishing them with relevant information via the MS Trust. For those who were experiencing stability with their MS they perceived the App as less useful.

I think it would be good for somebody who has just been diagnosed, to gauge how they're feeling and what symptoms and things that they've got, because I think at the beginning you just don't realise you have all these weird symptoms that you don't know that's necessarily associated to the MS. So I think to give them a bit of picture I think it would be really good. FG3 280322-2

Yes, I think I'll agree with that, that actually it does seem to be most useful for when you've been newly diagnosed and things are changing and you're getting used to it, but for us, like longer-term patients, things are a bit more stable and not changing so much, yes, it doesn't feel like it added much value. I mean, how I'd describe it is, I guess it's a bit of a help setting out trying to track your symptoms, on MS and how you're feeling. So I guess that's how I'd describe it. FG3 280322-3

I would agree with the other two. I think it's so useful at certain points in time, like when you're having strange symptoms that you can't really describe when you're asked face-to-face, so I was writing about things like it was like my legs were on fire, and this happens mostly at this time of day, or the night, or this is constant. So I think with an actual relapse it's probably very useful to be looking at other times. FG3 280322-1

Honestly, my use of it has been very limited. When I first got the link to it, I signed in and I did a few of the surveys, and things like that. That's not a criticism of the app itself. It's that I've not had a relapse in several years now, and even the initial MS symptoms that I had, they weren't very severe. Although technically, yes, I have MS, it really hasn't impacted my life in a major way, so I don't really feel the need to monitor myself so much in that way. I can see how it would be useful or could be useful, if you had more active symptoms and felt like you needed to more closely monitor your condition, or just your general well-being, as well. FG5 310322

... I can see how it could be a useful tool for people who, their MS, or whatever other condition it is, is more active. More present in their day-to-day lives. Definitely, yes, I would log in that way. For someone like myself, where, fortunately, it has not really been an issue, it's going to be of less use, but that's just my personality, as well, because I've not really had the relapse and things FG5 310322

It was interesting because on the better days, I tended not to think so much about using it. On the days when I was feeling oh, then I thought right, I'm on the app. Ind1 310322

One design implication flowing from this is a requirement for greater personalisation of the App to enable the patients to customise it to match their stage of illness or desired frequency of use. Individualisation of an App is, according to the marketing industry[5], 'craved by App users. The current version did allow surveys and events to be chosen by the patient, but, from the evidence of previous comments, this was not clear to them from the onboarding process. The following comment underlines this requirement.

...if it was more streamlined, and something which it's kind of easier to update, just recent changes and is not something which looks like - it did seem onerous what it was asking for. It is wanting you to put in a lot of stuff there, which when you're living with MS you can't be bothered with that. When you're newly diagnosed then it's all new, and maybe you can FG3 280322-3

8.43c MS friendly?

A couple of patients made pertinent comments concerning the usability of the App for people living with MS.

It is a good way of tracking your moods, what you've eaten or what you've not eaten or what you've forgotten to eat. I don't know how to describe it, it's nice having your own little personal journal to look back. I think it could be made easier. I don't know whether it's just me being thick, but I do think it could be made a lot MS-friendlier considering we have a lot of cognitive problems and memory problems FG4 310322 1

I'd just like to flag accessibility issues, like this is designed for people with MS, but things like dexterity makes you different, so being shorter and more concise means that we would be able to - like I wouldn't fill it in on my phone. I struggle to do it on my iPad, and things like that, just to tick little boxes and things like that, if you've got tremors in your hands, it's really difficult. Then also the fatigue, I'm just not sure how much you've thought of it in terms of using it when you've got the various symptoms of MS. FG3 280322-1

8.43d Notifications

Concomitant with an MS friendly design is the facility of the App to remind the patient they need to attend to it. Notifications are common to most Apps and our patients appeared surprised that this feature was absent. Moreover, there is evidence that such 'push factors' (Druce et al, 2019) can promote greater patient engagement with the device in question.

From a personal point of view, you know like when you've got your Android phone and you've got your email messages coming up, or Facebook messages and it gives you a ping? Well, if I hear a ping, I automatically pick my phone up and open it. That's what I could do with on this website. If I got a ping, a notification noise, something FG4 310322 2

Do you know what, love? Yes, you're dead right. Let it ping, so let me know that you've accepted it. You've added it to my diary, for want of a better word, but also to ping me to say, 'Excuse me, it's time for you to fill in your diary.' FG4 310322 1

Yes, that actually would have prompted me to use it more, so to have that nod to pick it up, because it's too easily out of mind. FG5 310322

8.43e Repetition

A recurring theme from the patient interviews was that the App's questions were repetitive. Patients perceived that they were being asked the same question but in a slightly different way. This is a burden on the patient and one and that is common in poorly designed Apps. Evidence from Druce et al (2019) suggests that data collection from a device has to be balanced: it needs to be comprehensive enough for the purpose of the device but as parsimonious as possible from the patient perspective. Indeed, if this balance is not found then it is likely to impact negatively upon patient retention.

I think less of the surveys. Is there about six surveys? No, there's six. How is your mood? I don't think we need to fill in six how is your mood. I think from that respect - okay, the diet and everything, and maybe what you're doing, the exercise, but we don't need a mood thing for every one. To me, I think you just need maybe one mood, how you're feeling today, how you're not. It was just the repetition of the mood was I found that really - you know how I feel. I've told you three times how many times I've been to the toilet or whatever. I don't need to tell you more than once. I think that repetition, I don't think there's the need for all those. FG3 280322-2

The questions were asked again and again or put in a different way. The same question, but in a different way which I didn't understand. FG4 310322 2

One thing which, obviously, we all know about MS unfortunately, we need consistency. We need to know when you click on something, 'Oh yes, that information, there it was yesterday,' it'll trigger things that we need all the time, and like x said, same questions, but worded differently. That's not good. FG4 310322 1

It is very repetitive, isn't it? FG4 310322 4

Not really. I'd like it to be a bit more user friendly and not be repetitive. We've gone through that already but, it's far too many questions. You could maybe condense the questions on the surveys. FG4 310322 3

8.44 Library content

One objective for this pilot study was to explore the ability of the App in meeting the information and support needs of MS patients, through use of meta-tagged data from the MS Trust. This was designed to work through an algorithm that matched the patient's digital profile with appropriate information supplied by the MS Trust which was then flagged in the App to the patient. The following comments reveal that this appeared to have worked and, in general, patients found it a useful feature.

I quite like looking at the information. There's a library section, so I tend to, if I've got a minute or if there is a …on there or if there's something particular I want to know, then I'll have a scroll through that. I quite like the idea of having the - because you could tick off what you'd read, so I knew what I'd… You can either go to it and see and say, 'Oh, I've read this,' so you know - because you know, memory's not brilliant, but you'd stayed in there, so again I found it useful to know what I'd read up on and I could go back and it was highlighted what I'd read. I found that useful. FG1 240322-2

I've just been using the well-being app, really. I've looked at the link to articles, which has been useful; I know I can get these other resources. I just came across them. I know you're prompted to look at some every day or whenever you log on, but I didn't go to them all, I don't think; I just chose ones that I was interested in. FG2 280322

I'm trying to think which one I saw now. I can't remember which one I looked at, but I obviously know they were on there, because I realised they were there. I probably had a brief look at one or two I think, but yes, I think the articles are good. Like I say, for anybody new to MS I really do think it is really good. FG3 280322-2

… I thought the other thing that was really interesting on it was the examples of reading. The reading that you can do about it, because there's titles of books and journals on it, which I found really useful. Ind1 310322

I've just got the app open … Under my recommended content it's got foot drop, which isn't something I'm experiencing at the moment, but I must have put it in as a pervious symptom, and then some other things. So it's on the login page. FG3 280322-1

It was the patient's digital profile which prompted relevant articles. For some patients there was no recommended content which may have been due to the onboarding highlighted above.

I didn't access any articles. Like I say, I think - I mean, I think I might have missed something, because I didn't see any articles. I saw the section on the front page saying about recommended content, and it just said there's no recommended content for you. I'm like, okay, then. FG3 280322-3

Oh yes, 'There are no library articles that match your profile.' Is that because I've not been putting enough stuff in my profile for now? FG4 310322 4

8.45 Optimum usage

This was a question posed by the interviewer. Optimum usage ranged, as the comments below illustrate, from daily to once very couple of months. The individual circumstance of the patient, their level of illness for example, along with the design of the App, is, as we have discussed above, likely to be the determining factors in their response to this question.

If I could speak into it, rather than actually typing in nutrition and - I would probably use it daily. FG1 240322-2

Yes, I think daily is too much, I think. For me, every other day FG4 310322 4

I think twice, three times a week, I think I'd use it, sort of thing. That it's going off how I've used it through this time. I'm thinking probably twice, three times a week. FG4 310322 2:

I think so, yes. It would, it'd be say, maybe like twice or three times a week. FG4 310322 3

Yes, I would do it weekly. Daily, I would find - it sounds awful - I would find it a grind, but when I know - I missed the last few minutes because it cut off and I came back on - but I think every day the same would be just too much, so I would say once a week FG1 240322

Certainly, for me, weekly is way too often, yes. In my opinion, monthly would be sufficient I would have thought. FG3 280322-4

I would say every one to two months, I could see doing it, maybe. Yes. FG5 310322

8.46 Support

The patients interviewed here were largely indifferent to being supported once they were using the App. Clearly, non-users' perspective would possibly be more instructive here. However, one or two patients mentioned a preference for reassurance at certain points, the comment below is indicative of this need:

Yes. Really, I could have done with someone to say, 'Yes, you're doing this right,' or, 'Try it this way.' Even, like as I say, I was expecting an app, now I access it from the email, which seems to be what everybody does now, but I didn't know if that was right. I would have liked someone to say, 'Yes, you doing this right? Try this or do this or…' FG4 310322

8.47 HCP interviews

Two HCPs were interviewed. The primary focus of their involvement in the project was recruiting patients to use the App. Consequently, the interviews are mainly concerned with the issue of patient engagement.

It is worth noting, to begin with, that both HCPs were enthusiastic about the project's objectives:

I think overall the idea of the app is amazing. I think it's great for patients. 22222

MS patients do get brain fog. It is a thing, and their memory can be shocking. I just don't feel like they get enough out of the consultation visits, which are annually. Obviously, because of COVID, some of them haven't been seen for a couple of years face-to-face. Obviously, I'm not a patient but I just see it from the patient's point of view. It's just great to keep a track on how they've been, just to get that more out of the consultation. If you go on a good day and your doctor says, 'How are you?', 'Yes, I'm great. Everything's great, positive,' whereas with the app, filling the app out, actually, 'You weren't so great last month. Why was that?' I just think they get so much more out of the consultation. In that respect, I do think it's a great idea. 310322

Alongside benefits to patients, they could also see how the App could benefit the work of HCPs.

I think for us as a general, it gives us an overall picture of how the patient's MS is on a day-to-day basis. It's not just that capture shot when we see them. It's every day because they only do ring when they are in crisis. If a patient has got... Relapse and remitting, they might be constantly having relapses, so for patients like that the nurses will get to know very, very quickly, but the patients who have got a different type of MS, they might not see them. They might not see them for a year so, and it's good so then the next time they see them, it's not like, 'Oh, I can't remember who this is.' If they've got the app, they can actually see that because the app can also... There's a picture. They can put pictures on there and stuff. I think it's good because... I know notes are great, hospital notes, but to get that personal element... If I go to a doctor's appointment and I say, 'Oh, I do yoga and I do exercise,' the next time I go, I know the doctor has got a massive list, but next time I go I'd like them to say to me, 'Oh, how are you getting on with your exercise? How are you getting on with your yoga?' I think the app does assist us with that because it shows what they do. Some of the patients were entering that they were going to church and stuff like that, so it just gave a bit more of a personal element to it. 22222

But, like many participating patients they could see the obvious downside of the what the 'App' delivered in practice.

The fact that it wasn't an app, I thought, was the worst idea ever. I knew people wouldn't engage because of that reason. Very time-consuming, not easy to access. MS patients do have a problem with dexterity, so fiddling around trying to access something can be tricky anyway. You have to make it easier that they can just click on an app. That was one of - that was the main - that was the most feedback I had, negative feedback, I'd say. 310322

8.47a Patient engagement

The issue of recruiting patients and then maintaining their use of the App proved to be the most challenging aspect of this project. It took three months to persuade 50 patients, out of 250 initially contacted to agree to use the App. Of this 50 only 25 went on to use the App. As Figure 3 (above) demonstrates 15 had used it for more than a month and, of these, only 7 had gone on to use it for more than 4 months.

The following comments illuminate some of the difficulties involved in engaging patients with this project.

The method of contacting patients here, that is, in the first instance by postal mail followed up by a phone, proved to be resource intensive.

It's a full-time job, personally. It's the recruitment side, sending out 250 packs takes a very, very long time. You having to then ring those patients. If they ring and they answer, that was like finding a diamond on the floor! The first time you rang... It took a very long time and then people would say to me, 'I'll help you. I'll help you,' but then they didn't have access to their patient centres, and I would have to download the list, get the patients' numbers for them and give it to them. 22222

I think it was also the fact that patients work. Fair enough. I work 8:00 - 4:00. On paper I work 8:00 - 4:00. I then changed to 7:00 - 5.00 thinking that would help and it didn't. Then some days I was working till nine o'clock at night just to get these patients. Some patients were saying, 'Yes, I will do it, but I work and I'm not available until seven o'clock at night.'22222

One of the HCPs thought that email contact could be more efficient, however, the patient record at Salford Royal did not collect all patient email addresses.

Yes, so it's separate, but in the EPR bit, which is the patient records, there is no email. That would have really helped me if I did know their email because then I could have just sent it out without trying to ring. 22222

A further potential problem with email is highlighted by this HCP.

Again, like for us we sit logged into our computers all day. It's part of our life. If an email comes up, we read it straight away, or we glance at it. When you're emailing the general public, some people don't log on to their emails for weeks at a time. They don't use technology like we do in our jobs. I think that's against us as well. 310322

8.47b Possible solutions

The HCPs offered constructive suggestions to improve engagement in the future. One such suggestion involved embracing the digital and making the recruitment process entirely electronic.

'It would better if it was on the app.' You know when it asks you… For your terms and conditions and all that, do you agree? Then you agree and it's like a consent form on there. I think it would be the best way to do it and it's done. Then it's electronic. It saves to the patient's file, and we've got it. 22222

I would have expected this all-singing, all-dancing app, and I could present it to the patients. 'Look, we've got this app. Just scan this QR code here, it'll download it on your phone. Create yourself a user name and login, and just see how you go with it. If you've got any questions, give me a ring.' It should have been that simple. 310322

What I would do is, I'd have leaflets made up with a QR code on them. Very simple, very easy. I'd hand the leaflets out. I'd get the consultants to have a pile of them on the desk, hand them out to patients. 'We're doing this new app, have a look at this.' I'd do it like that. Contacting them over the phone doesn't work. It's cold-calling, isn't it? I'd have that as my first point of handing them out as a QR code, something easy, eye-catching, and you can just scan the phone and the app comes up. 310322

They were conscious that such solutions may exclude the digitally illiterate and were keen to offer alternative ways of involving those may be 'hard to reach'. One proposal was to utilise 'social' events in local areas.

I know it's quite a lot of work on our side, but actually doing some group work, you know if there was a group of them, like ten people because those type of people are the people who actually don't have any contact with the outside world, in my opinion. Meeting maybe in a local library or somewhere like that which isn't far from their house… Trying to have a bit of a social type event, bringing people… Say, 'Come along to this event.' I mean now COVID's over, we might be able to get away with that. 'There'll be tea or coffee and biscuits there and we'll introduce you to this app, this new service that we're promoting. There'll be people there to talk to you about how you might use it and if you've got difficulties how…' Do you think that might be a better way? 22222

Another suggestion was to exploit trusted relationships more.

It's like when I've been trying to onboard people this time around, some of them have been a bit like, 'Oh, don't really know.' As soon as I say, 'It's Dr Rog,' and they're like, 'Oh yes, he's my consultant. I'll do it then if it's Dr X,' that instantly makes people believe in it. Even if we could just have the doctors do a little video call. I know it's cheesy, but people like a bit of cheese. 'Hi, it's Dr X from Salford neurology.' They've got a massive amount of respect for him. He's a fantastic doctor. He knows MS. He's passionate about it, and… They're more likely to do it rather than me saying it, because they just think, 'Who are you?' That's just life, isn't it really? I think that would make a massive difference.

9.

CONCLUDING DISCUSSION

The potential for digital technology to transform healthcare is well documented, yet a challenging gap between this potential and reality remains. The literature (see Appendix 1) largely bears witness to this dichotomy and the dearth of robust evidence to support the case for transformation. This evaluation not only testifies to these challenges but also addresses the lack of evidence, albeit it partially. The partiality of the evidence here is largely a function of the extraordinary circumstances within which this data was collected.

The SARS-COV2 pandemic propelled the project to be redesigned and to work within the environment of pandemic strained resources at Salford Royal Hospital. Backroom staff responsible for patient recruitment appeared ill-equipped, from a time and information perspective, to fulfil this task effectively and dedicated project management was not in place for the whole of the project.

Within these constraints 52 patients, from an initial sample of 250, consented to use the App, meeting the project's minimum target of 50. Figure 1 illustrates the laborious rate of recruitment – around two fifths (21) of the total were only recruited towards the end of the project. The flow chart in Figure 2 (above) demonstrates how this affected usage of the App: only 32 logged on and of these 25 went on to complete any surveys or events on the App. Out of this 25 only one used it for 6 months. As such, the low numbers militate against drawing any definitive conclusions about usage of the App, including how it may have promoted self-efficacy amongst users. Consequently, the quantitative data can only be indicative of what potentially could be collected, and the qualitative data has assumed greater importance than was originally envisaged.

The self-efficacy results demonstrated a fall, between the baseline and endpoint measure, not only in the average but also largely in the individual GSE score, however these findings need to be read with caution. This is a very small number of users of whom only one used it for 6 months and that person was logging on around once every 3 weeks (see Fig 2 above). As Jongen et al (2020) noted, it may not be justified to expect a short-term improvement in empowerment in terms of self-efficacy for first time users of a digital healthcare device.

So, extant research suggests that more users using the App for a greater period of time than our pilot here is necessary to provide a definitive view of the App's capacity to promote self-efficacy. The onboard metrics are similarly sparse in quantity and preclude drawing any substantive conclusion about how the App has been used. However, it is potentially indicative that just under a third of the users stopped using the App within the first week. This may speak to a requirement for real-time monitoring of use and ongoing support for users. Moreover, a greater understanding of the context within which these users used the App, is provided by focus group interviews (below) and may illuminate some reasons for poor patient retention and the consequent quantitative findings.

The qualitative data, underscores learning points that should prove invaluable to future iterations of innovative projects. As with all cliches there is a grain of truth in the old maxim that 'learning to fail is a virtue but failing to learn a sin'. Accordingly, the remainder of this concluding discussion will emphasise the learnings furnished from this project.

The first learning point is something the project appeared to do well. This concerns inculcating a culture that convinces the staff responsible for delivering the project, and the wider MS clinical team, of the merits of the endeavour. Cripps and Scarborough (2022) argue that changing and managing an appropriate culture within the workforce is critical in sustaining innovative development. The evidence gathered here suggests that all the staff involved were convinced of and attracted to the potential of the App. The following comment from an HCP is illustrative of this, 'I think overall the idea of the App is amazing. I think it's great for patients.'

Learning point 2 is concerned with the submission of an appropriate and timely NHS ethics application. It is well known that researchers should build in appropriate time to navigate NHS ethics, however navigating ethics and governance at both local and national levels immediately post covid proved challenging and time consuming which impacted adversely on the project's timeline and the time remaining to recruit patients. The necessity of switching to a socially distanced mode of recruitment and onboarding added further delays. Pre-covid, participants would have been recruited in clinic waiting rooms where there are opportunities for questions and to generate interest in participating. Clinics were conducted by telephone and hospital information systems did not support email communication resulting in postal and telephone recruitment. The ethics submission also served to constrain how the project might recruit patients. So, for example, the project was ethically unable to co-opt the MS Trust or the patient facebook group in the recruitment task. As such care should be taken to write the submission that provides the project with a reasonable scope of recruitment options whilst still maintaining patient confidentiality.

The initial co-creation workshops with PwMS worked well to produce a list of design specifications that would otherwise have gone unnoticed. What worked particularly well here was the collaboration with the facebook group established and run by patients. Given that all the redesign recommendations flowing from the workshops could not be implemented it was this group who ensured that it was PwMS who determined the re-design priorities **(see Appendix 2)**. In hindsight more resources should have been directed to this group to ensure their continued involvement over the lifetime of the project to support participants and ensure continuous feedback to the project management board. As one participant commented, '...I think what made a difference because... set up a Facebook group where I thought we'd all be giving feedback to each other...' **This is learning point 3**. The development of patient advisory groups (PAGs) is seen as fundamental to the success of similar projects (see, for example: Druce et al,2019).

Appropriate resourcing of the project is **learning point 4**. Lack of such resources was apparent in at least two areas which impacted adversely on the project. The first was in patient recruitment where the staff at Salford Royal often appeared overwhelmed by this task as one mentioned, 'on paper I work 8:00 - 4:00. I then changed to 7:00 - 5.00 thinking that would help and it didn't. Then some days I was working till nine o'clock at night just to get these patients.' This was partly a function of the SARS-COV2 pandemic that forced the abandonment of the original notion of recruiting patients face-to-face in clinic. Staff were obliged to contact patients first by postal mail and then a follow up phone call neither of which were cost effective. Due to social distancing, there was also insufficient input from MS nurses who had, unlike the staff given the responsibility for recruitment, knowledge of their patients' personal circumstances that would have helped with recruitment. The second area that required appropriate resourcing was a dedicated project manager for the lifetime of the project.

Fully exploiting appropriate digital avenues for recruiting patients is **Learning point 5**. As one HCP pointed out, 'It would better if it was on the app...Look, we've got this app. Just scan this QR code here, it'll download it on your phone. Create yourself a username and login, and just see how you go with it. If you've got any questions, give me a ring.' It should have been that simple'. The QR code could be sent via email, if patient email is available, or printed on a leaflet to be distributed at clinics for patients to peruse.

Of course, this method could well exclude those lacking in digital confidence. **Learning point 6** is that specific, targeted methods and resources must be applied if the socio-economically disadvantaged or digitally illiterate are to be included in any such project. One HCP suggested, 'I know it's quite a lot of work on our side, but actually doing some group work, you know if there was a group of them, like ten people because those type of people are the people who actually don't have any contact with the outside world, in my opinion. Meeting maybe in a local library or somewhere like that which isn't far from their house... Trying to have a bit of a social type event...'

Learning point 7 is closely related with the previous two points and emphasises the importance of trusted relationships in patient recruitment. This might involve, as noted above, using the MS nurses to build upon their relationships with patients or as an HCP suggested, exploiting the doctor – patient relationship, '…if we could just have the doctors do a little video call. I know it's cheesy, but people like a bit of cheese. 'Hi, it's Dr X from Salford neurology.' They've got a massive amount of respect for him. He's a fantastic doctor. He knows MS. He's passionate about it, and… They're more likely to do it rather than me saying it, because they just think, 'Who are you?' That's just life, isn't it really? I think that would make a massive difference.'

Moving away from recruitment to the problem of patient engagement and retention is the remit of learning point 8. This point underlines the importance of patient onboarding to the App. The marketing industry contend that a 'good' onboarding can result in up to a 50% increase in user retention for the App in question. Testimony from participants suggested that the onboarding process did not achieve this and potentially explained the low or infrequent usage of the App. 'Yes. I'm not sure it was explained to me very well - but I might be wrong, though. That could just be me. I've not used it every day; I don't know if that was the intention?' It may also partly explain the low uptake of the MS Trust library content. Only 5 users accessed the MS Trust site. For some patients there was no recommended content which may have been a function of the poor onboarding. Part of the problem here was that the 'onboarding' process was necessarily conducted over the telephone with individual participants when a face-to-face interactive group session was the ideal. Alongside this the process emphasised learning how to use the device at the expense of explaining how the App could be of benefit to the PwMS. Greater attention and resources must be applied in future to ensure that this process is fit for purpose.

Notifications are common to most Apps and our patients appeared surprised that this feature was absent from this App. 'Yes, that actually would have prompted me to use it more, so to have that nod to pick it up, because it's too easily out of mind.' This is learning point 9 and there is evidence that such 'push factors' (Druce et al, 2019) can promote greater patient engagement with the device in question.

Learning point 10 is about reducing 'participant burden'. This, according to Druce et al (2019) increases patient retention. Several features of the digital tool used here failed to do this. Firstly, the device was not an App. It was a web link that could be accessed from a mobile device, but it was not designed specifically for this purpose. As such many of the participants used their laptops instead with some suggesting they might have used it more if it had been an App on their phone. Another recurring theme from the patient interviews was that the App's questions were repetitive. Patients perceived that they were being asked the same question but in a slightly different way, 'The questions were asked again and again or put in a different way. The same question, but in a different way which I didn't understand.' This is a burden on the patient and one that is common in poorly designed Apps.

Learning point 11 is a segue from 10 in that the client should always ensure the product they receive from their technology partner is the product that was promised. Related to this is learning point 12 which emphasises a requirement for real time data from the device to monitor patient usage so staff can contact patients and provide support if required. Learning point 13 similarly states a requirement that the device should enable the rating, by PwMS, of the bespoke meta-tagged information (from the MS Trust), pushed to the PwMS based upon their initial digital profile of symptoms and other MS-related characteristics.

Learning point 14 identifies the need for a consistent set of staff working on the project. Here, staff changed throughout the project both at SRFT and at the technology partner which hampered communication and product delivery.

As noted above, individualisation of an App is, according to the marketing industry[6], 'craved by App users.' This was underlined here by participants in a number of ways and comprises learning point 15. Several participants commented that the App's features were less appropriate to PwMS who had been living with MS for a while, but whose illness was relatively stable. This comment is illustrative: '…it does seem to be most useful for when you've been newly diagnosed and things are changing and you're getting used to it, but for us, like longer-term patients, things are a bit more stable and not changing so much, yes, it doesn't feel like it added much value.' Alongside this another mentioned that given dexterity was an issue for PwMS the App should have the facility to receive oral instruction: 'If I could speak into it, rather than actually typing in nutrition and - I would probably use it daily.'

The final learning point 16 concerns optimum usage. If all the prior learning points were to be applied, then it is more likely that patient engagement and retention with the digital device would be increased. However, evidence collected here suggests that patients would still use the device as frequently as it suited them and their circumstances. When asked about how often they would use such a device – when fully customised and integrated into their patient record at the hospital- the responses varied from 'daily' to 'once every month or two.' So the lesson here is that as long as this is satisfactory for the patient and their clinical care, and they do remain engaged with the device, then their frequency of use may be less significant.

To conclude, as prior research has shown **(see lit review Appendix 1)** piloting innovative digital projects within a healthcare context is a challenging undertaking. Notwithstanding the adverse circumstances wrought by the Covid pandemic - that effectively prevented the project from achieving a number of its objectives - this pilot project has managed to empirically foreground a number of invaluable learning points that can only serve to strengthen similar future projects. As such this pilot should be seen as a qualified success.

APPENDICES

Appendix 1

Literature review

Introduction

It is now a normative statement to describe the potential for digital technology achieving transformative benefits in healthcare and this has long been reflected in national policy statements from the Department of Health (2010, 2020). Yet a challenging gap between this potential and reality also remains. The literature largely bears witness to this dichotomy and the dearth of robust evidence to support the case for transformation.

In general, digital applications are part of the digital transformation in healthcare, which will see the integration of technologies such as advanced analytics, machine learning, and artificial intelligence (Baltaxe 2019). Digital transformation in healthcare can lead to improvements in diagnosis, prevention, and therapy. It enables Health Care Professionals (HCPs) to apply an evidence-based approach to improve clinical decision-making (Gopal 2019) Further examples are the provision of comprehensive information and the rapid exchange of reports and information between patients, experts, and medical centres. Especially in the case of complex, unpredictable, and chronically progressive diseases such as MS, digitalisation and electronic health (eHealth) systems can help to better diagnose, monitor, and thus optimally treat individual patients (Haase, 2018).

In a similar vein, Dunn & Hazzard (2019) describe the current, digital technologies and how they represent enormous promise in the building of digital health literacy skills and improved health outcomes in patients with cardiovascular and other chronic conditions. This is a promise, they contend, that is yet to be fulfilled. The cost-benefit equation was examined by Henderson et al (2013) who conducted a large randomised controlled 12-month trial of telehealth in the UK and concluded the intervention incurred additional costs (for participants and GPs) for only a very minimal gain in quality adjusted life years.

Moreover, there is a prevailing view (Asthana et al, 2019) that the UK is good at generating innovations but poor at adopting them. Despite a proliferation of eHealth technologies, few meet robust evidential requirements. For example, NHS Digital (a division of the NHS) is the lead national delivery partner for improving the use of data and digital technologies in the health and care system. Yet, its Apps Library showcases a fraction (74 in 2019) of the 50,000 medical apps that were available in the Apple App Store worldwide. One explanation for this, Asthana argues, is that the eHealth sector is dominated by small and medium sized enterprises (SMEs) many of which do not have the capacity to address the technical, clinical or cost-effectiveness standards required by NHS Digital and NICE. Another contention, from a survey conducted by Incisive Health International (2018), is that a lack of integration with formal health services means Britons are less likely to use Health Apps to manage a health condition, store personal medical data or contact a health professional than people in the other countries. This lack of integration may also be a function of the lack of connectivity between and within the NHS (Long et al 2013).

The remainder of this review focuses on the evidence relevant to this project and looks at the available literature on digital applications and self-management of chronic conditions particularly for people with Multiple Sclerosis. It also considers the available literature on patient engagement with digital applications.

Self-management

Self-management of health implies management of activities contributing to health including physical activity, nutrition, stress, sleep, medication intake, and management of symptoms (Morgan et al., 2017; Powers et al., 2017). Self-management for chronically ill patients is highly suggested and even required, especially for patients who see their specialist occasionally and need to manage their condition daily (Wagner et al., 2001). Self-management has also been shown to play a role in the reduction of disease exacerbations in chronically sick patients and improve adherence to rehabilitation (Bodenheimer, 2002; Gallagher et al., 2008; Duscha et al., 2018). This is achieved by continuous and unobtrusive monitoring of the patient's health state while enabling the patient to follow an almost-normal daily life routine. However, the efficacy of digital applications in promoting self-management for the benefit of patients and clinicians remains unclear as the following demonstrates.

A systematic review was conducted (Morton et al, 2017) to understand the experiences of patients and healthcare professionals (HCPs) using self-management digital interventions (DIs) for chronic physical health conditions. The review found that patients monitoring their health felt reassured by the insight this provided and perceived they had more meaningful consultations with the HCP. These benefits were elicited by simple tele-monitoring systems as well as multifaceted DIs. Patients appeared to feel more reliant on HCPs if they received regular feedback from the HCP. HCPs focused mainly on their improved clinical control, and some also appreciated patients' increased understanding of their condition. Patients using self-management DIs tend to feel well cared for and perceived that they adopted a more active role in consultations, whilst HCPs focus on the clinical benefits provided by DIs.

McCabe et al (2017) evaluated the effectiveness of interventions delivered by computer and by mobile technology versus face-to-face or hard copy/digital documentary-delivered interventions, or both, in facilitating, supporting, and sustaining self-management among people with COPD. Their systematic review suggests that interventions aimed at facilitating, supporting, and sustaining self-management in people with COPD and delivered via smart technology significantly improved health-related quality of life and levels of activity up to six months compared with interventions given through face-to-face/digital and/or written support, However, this improvement may not be sustained over a long duration. The only included study that measured outcomes up to 12 months highlighted the need to ensure sustained engagement with the technology over time. Limited evidence suggests that using computer and mobile technology for self-management for people with COPD is not harmful and may be more beneficial for some people than for others, for example, those with an interest in using technology may derive greater benefit.

In Korea, a highly connected country, with a high chronic care burden. A systematic review of mHealth interventions for the self-management of chronic diseases (Yi et al 2018) found eleven studies that showed mHealth interventions to be effective in improving self-management behaviours, biomarkers, or patient-reported outcome measures associated with chronic diseases. None reported negative impacts of mHealth on selected outcomes.

In a 2019 study involving 81 participants, Setiawan et al, developed an adaptive mHealth system capable of supporting long-term self-management and adapting to the various needs and conditions of Persons with chronic conditions and disabilities (PwCCDs). They found it useful for PwCCDs to prevent secondary complications However, it proved challenging to provide desired self-management support to PwCCDs for several reasons. First, there are many different chronic conditions, and these vary in severity and differ broadly in terms of characteristics. Consequently, PwCCDs have very diverse needs with regard to self-management support. Second, the phases of chronic conditions and life circumstances change over time. Third, the majority of chronic conditions and disabilities are inherently long-lasting and generally lifelong. Therefore, the self-management will be long-term as well. As a result, it is a challenge to keep PwCCDs engaged and interested in long-term self-management.

Another, more recent, systematic review (Scott et al 2020) examined the evidence of Smartphone health applications used to assist patients in chronic disease self-management (these included: asthma, chronic obstructive lung disease, diabetes, chronic pain, serious mental health disorders, alcohol and substance addiction, heart failure, ischaemic heart disease, cancer, cognitive impairment, chronic kidney disease). It concluded that the effects of such Apps on patient outcomes are uncertain, as are design features that maximise usability and efficacy. Indeed, consistent evidence of benefit was seen only with Apps for diabetes, as measured by decreased glycosylated haemoglobin levels (HbA1c). Evidence of clinical benefit of most available apps is very limited. Design features that enhance usability and maximise efficacy were identified. Personalised information, real-time feedback and access to expert consultation when required are features highly valued

by users.
From a more methodological perspective Larbi et al (2020) conducted a systematic review examining criteria for evaluating digital diabetes self-management interventions and found the most evaluated criteria for Apps were cognitive impact, clinical impact, and usability. Feasibility and security and privacy were not evaluated by studies considered of high confidence in the evidence. They concluded there were few studies with high confidence in the evidence that involved patients in the evaluation of Apps and digital interventions for diabetes self-management. Additional evaluation criteria, such as sustainability and interoperability, should be focused on more in future studies to provide a better understanding of the effects and potential of Apps and digital interventions for diabetes self-management.

People with Multiple Sclerosis (PwMS)

With a more specific focus on digital interventions with people with Multiple Sclerosis (PwMS) Wicks et al (2015) claim that E-health is enabling the development of an increasingly robust ‘learning health system’ for multiple sclerosis. Patient-centred data and tools should better empower patients and improve health outcomes by enabling greater self-management of care. Lavorgna et al (2018) illustrated advances in digital technology that can improve clinical management and in motor and cognitive rehabilitation of PwMS. They also advocated future development of the “digital case manager” as a new figure to coordinate clinical management and care of pwMS.

In a more qualitative study, Wendrich et al (2019) conducted in-depth interviews with seven adults with MS before and after participation in a study in which they used an activity tracker and an MS-specific smartphone App for 4 weeks. They inquired about experiences with the tools in daily life and needs and wishes regarding further development and implementation of digital self-monitoring for people with MS. The smartphone App and the activity tracker increased respondents’ awareness of their physical status and stimulated them to act on the data. Challenges, such as confrontation with their MS and difficulties with data interpretation, were discussed. The respondents desired 1) adaptation of digital self-monitoring tools to a patient’s personal situation, 2) guidance to increase the value of the data, and 3) integration of digital self-monitoring into treatment plans.

Matthews et al (2020) identified more than 1000 smartphone Apps for medical self-management, with more than 100 unique applications, of which almost a quarter are designed for problems of PwMS. A few promising early studies have reported combining wearables with internet-based interventions for gait rehabilitation (Motl, 2011; van Kessel et al, 2016; Tallner et al, 2016). Pilot data suggested that repeated use of MSmonitor (an interactive, Internet-based program for the self-monitoring, self-management, and integrated multidisciplinary care of patients with MS) led to an increase in health-related quality of life (QoL) and helped patients to self-manage fatigue (Jongen et al 2015). In a subsequent survey of 55 patients with MS, MSmonitor has been shown to improve patients’ insights into symptoms and disabilities and improve the quality of nursing care they received (Jongen et al 2016). Feasibility was confirmed in a recent randomized clinical trial (Paul, 2019) and early efforts using a smart tablet-based app for dexterity training have also been described [van Beek, 2019)]. In the future, ‘gamification’ of rehabilitation (and testing) apps may promote adherence (Bove et al, 2019) and there also is a potential to extend capabilities using robotics (Dixie et al, 2019).

However, striking a now familiar note, Marziniak et al (2018) concluded, from their systematic review into e-health solutions for PwMS, that, data from large, controlled, multi-centre trials are lacking so it is difficult to draw objective conclusions about the clinical benefits associated with each technology.

Self-efficacy

Self-efficacy is the self-belief that an individual can manage his/her daily life and put in effort to get the desired behavioural and health outcomes (Bandura, 1977). General self-efficacy entails general attitudes and self-beliefs to cope with a variety of difficult demands in life. Self-efficacy of health is a complex psychological concept that varies over time for the same person, according to their current health state and treatment plan. It is highly correlated with the patient’s self-management efforts and hence their health outcomes (Strecher et al., 1986; Sarkar et al., 2006; Ross and Mirowsky, 2010; Bethancourt et al., 2014). There is a large role of self-efficacy of activities contributing to the long term health state of patients (Lenferink et al., 2017; Cameron et al., 2018).

Self-efficacy has been shown to improve self-management, in direct and indirect ways. A cohort study focused on a chronic disease self-management program found that after 7 weeks of a self-management program with an emphasis on self-efficacy (including problem solving, decision making and confidence building skills), participants made statistically significant improvements in their health status, self-efficacy and health behaviors and had fewer emergency department visits (Lorig et al., 2001). This study illustrates that programs that have a self-efficacy focus can help patients improve their self-management. Self-efficacy can also improve self-management in a more indirect manner. Self-efficacy can lead to an in increase in self-belief that can spillover across other domains of life, contributing to health indirectly, e.g., having better communication and better quality of social interactions (Lauren et al., 2016). It has been shown that patients with greater quality of social interactions are more successful at self-management (Reeves et al., 2014). Additionally self-efficacy can allow individuals to build on successes, tackling easier behaviors successful and spilling over in attempting more challenging behaviors (Lauren et al., 2016). Although self-efficacy has been shown to improve self-management, the rudimentary patient education provided by the current health system is not sufficient to leverage and improve this self-efficacy, hence so many patients relapse over time (Lorig et al., 2001).

The wide use of smartphones and wearables may provide a method for increasing self-efficacy and self-management in patients with chronic conditions, although there is limited research on its efficacy (McCabe et al., 2017). However, we still know little on the role of this technology on patients' self-efficacy of health-related activities and on if/how chronically ill patients use and experience the widely available smartphones/wearables (Wang et al., 2014; Hamine et al., 2015; McCabe et al., 2017).

Moreoever, Jongen et al (2020) concluded that for first-time users of the MSmonitor program and their health care providers, it may not be justified to expect a short-term improvement in empowerment in terms of self-efficacy, self-management, autonomy, or participation. Furthermore, a lack of effect on empowerment is not because of non-usage of the program components.

Design of the digital App is clearly important and Wulfovich et al (2019) conducted an explorative study (mixed method study involving 200 chronically ill patients) on the implications for the design of mobile apps and wearables to effectively support patients' efforts in self-management of health with a special emphasis on support for self-efficacy of activities contributing to health. They found that mobile apps for health and wearables have the potential to enable better self-management and improve patients' wellbeing but must be further refined to address different human aspects of their use.

Specifically, the Apps/wearables should be easier to use, more personalized and context-aware for the patient's overall routine and lifestyle choices, as well as with respect to the momentary patient state (e.g., location, type of people around) and health(care) needs. Interestingly they argue their findings point toward a strategy that is well known in the health communication field, which is tailored communication (Hawkins et al., 2008). They emphasise that their findings demonstrate that pre-conceived design ideas aimed at influencing self-efficacy do not correspond to what users want, as they show the necessity of having a design adapted to different personality traits in order to increase individual's self-efficacy.

Beyond self-efficacy, Wulfovich et al argue that user experience could be positively influenced and sustained by personalized solution in Apps and wearables, as well as by personalized feedback. Many behavioural interventions have shown that one size does not fit all and, in an argument that supports methods of patient involvement in design such as co-creation, emphasise the need to tailor the solutions to the individual needs. As mobile and wearables offer an unprecedented opportunity to tailor communication, as personal devices are able to collect data that can be used to this end. If tailored approach has been already proven successful on the web (Lustria et al., 2013), they contend that such a tailored design approach for mobiles and wearable is fundamental for the future.

Complementary, HCI research (Ayobi et al 2017; Guerts et al 2019) has highlighted the need for technologies that support people's sense of autonomy and sense of control in managing idiosyncratic MS experiences in everyday life.

Patient engagement

A compelling ethical rationale supports patient engagement in healthcare research. It is also assumed that patient engagement will lead to research findings that are more pertinent to patients' concerns and dilemmas. This assumption remains true notwithstanding the engagement method may vary from face-to-face, to analogue, to digital.

There have been a number of systematic reviews, over the last two decade, looking at engaging patients in healthcare research per se (Nilsen ES et al, 2006; Brett J, 2010; Mockford C et al, 2012; Domecq et al, 2014; Fergusson et al, 2018). The overall findings from these reviews are consistent in concluding that research dedicated to determining the best practice for meaningful engagement is still needed, but adequate reporting measures also need to be defined.

Before turning to the literature concerning patient engagement with digital healthcare tools, it is worth noting a cautionary statistic from the commercial digital applications industry. One of the most successful smartphone games of recent years, Pokémon Go (https://pokemongolive.com/en/) experienced a loss of one-third (15 million) of their daily active users within 1 month of the launch date (Siegal, 2016). Moreover, estimates indicate that across all industries (media and entertainment, retail, lifestyle, and business) the average retention rate was 5.7% after 30 days (Perro, 2018).

Notwithstanding this Irizarry et al (2015) demonstrated that patients' interest and ability to use patient portals is strongly influenced by personal factors such age, ethnicity, education level, health literacy, health status, and role as a caregiver. Health care delivery factors, mainly provider endorsement and patient portal usability also contribute to patient's ability to engage through and with the patient portal. Future directions of research should focus on identifying specific populations and contextual considerations that would benefit most from a greater degree of patient engagement through a patient portal. Ultimately, adoption by patients and endorsement by providers will come when existing patient portal features align with patients' and providers' information needs and functionality. Similarly, Dendere et al (2019) also found sociodemographic characteristics and medical conditions of patients were predictors of portal use. They also found patients' privacy concerns and lack of encouragement from providers were among portal adoption barriers while information access and patient-provider communication were among facilitators.

Druce et al (2019) documents two recently completed mHealth studies conducted within the Arthritis Research UK Centre for Epidemiology at the University of Manchester have had notable success with respect to recruiting and engaging participants for between 30 days and 12 months. The success of these studies is due to the considered strategies used to maximize participant engagement.

These include:

1 First and foremost, it is important to consider the use of **patient advisory groups (PAGs)**, who are well positioned to codesign the study by identifying potential barriers for participants and help craft possible solutions

2 Attrition is likely higher among people who experience functional/logistical limitations using the App. Thus, specific considerations must be given to the **suitability of the devices** provided for the target population.

3 It is essential that the study design considers the most **parsimonious data collection** protocol possible from a participant's point of view, while being sufficiently comprehensive to collect all data necessary.

4 Although some degree of **attrition** is inevitable in longitudinal research, it is likely that the attrition is greater and more rapid when participant burden (both in terms of frequency and complexity of data collection) is higher.

5 **Participant burden** may be reduced further by the use of passive monitoring. Passive monitoring is defined as a data collection technique that can collect relevant information without active engagement from the participant.

6 **Push factors.** Push factors to promote engagement may range from generic strategies, such as the use of automatic daily prompts or alerts for data completion, to a more intensive and bespoke process of real-time data monitoring and targeted completion reminders. Other factors that may push participants to engage may include ongoing study feedback, networking effects, and opportunities to interact with other participants within study communities.

7 **Automated reminders** and notifications typically are built-in features of mHealth studies and increase the chances of collecting the data required, because data entry not only is reliant on a participant's memory but also is prompted.

8 **Real time data monitoring and reminders.** If reminders are unsuccessful and participants have not completed data collection, it has been shown that real-time data monitoring and active chasing of participants (ie, sending targeted completion reminders) can be successful in preventing dropout and maximizing data completion.

9 **Personal motivation.** Individuals may be more likely to participate in studies of experiences that have affected them personally or in studies where they perceive a wider societal benefit .

10 **Study feedback.** In addition to a desire to contribute data to address the research question, PAG members highlighted that participants may wish to personally benefit from taking part in studies by receiving feedback on

(personal) study results.

11 **Network effects and community building.** The significance of creating a study community was highlighted within the Cloudy with a Chance of Pain study, in which various (optional) social media and support channels were also made available to participants to engage with the study team and other participants. Furthermore, participants were able to connect with the research team and other participants via the study team's presence on social media, including Twitter (@CloudyPain; 883 followers), Facebook (Cloudy with a Chance of Pain; 585 likes), and Instagram (@Cloudy_Pain; 49 followers). Finally, weekly newsletters and an online blog (https://www.cloudywithachanceofpain.com/blog) disseminated information about study progress and included guest articles from participants, charity partners, researchers, and funders. Importantly, by establishing the study community, it was possible to enable participants to feel empowered to share their experience.

12 **Personal contact and ability to obtain help.** In addition to the support provided by study communities, personal, as opposed to virtual, contact was highlighted as an essential provision for mHealth studies. In particular, QUASAR PAG members believed that having personal contact was important to make participants feel valued and more likely to complete the data collection protocol.

Cripps and Scarborough's (2022) recent contribution emphasises sustainability. They argue such an approach requires a shift in both thinking and practice when it comes to the spread and adoption of digital healthcare technologies. This requires less of a focus on the technology and more attention to the motivations, constraints and specific contexts that influence users and patients. This draws upon the work conducted by the Sustainable Healthcare Team at NHS England who have devised four 'pillars of insight'. Clinical insight involves not losing sight of the ultimate purpose of the innovation. Behavioural insight draws on a range of disciplines including psychology, sociology, and data sciences to understand how people might respond to new services or technologies. The aim is to "nudge" people so that evidence-based change is positively received by framing it appropriately in communications around the project. Process engineering is the third insight and the aim here is to make the process of applying the new technology or service as explicit, simple, and comprehensible as possible. Finally, knowledge management provides valuable insight on the evidence underpinning the need for change, and how best to deliver it.

BIBLIOGRAPHY

Albury, D., Beresford, T., Dew, S., Horton, T., Illingworth, J. and Langford, K. (2018) *Against the Odds: Successfully scaling innovation in the NHS. London: The Health Foundation.*

Asthana, S., Jones, R. and Shaeff, R. (2019) Why does the NHS struggle to adopt eHealth innovations? A review of macro, meso and micro factors. *BMC Health Services Research.* 19: 984.

Astin, F., Closs, SJ., McLenachan, J., Hunter, S. and Priestley, C. (2008) The information needs of patients treated with primary angioplasty for heart attack: an exploratory study. *Patient Education Counsel,* Nov, 73(2):325-332.

Alakeson, V. (2011) *Active Patient: The Case for Self-direction in Healthcare.* Birmingham: University of Birmingham Centre for Welfare Reform.

Ayobi, A., Marshall, P., Cox, A.L. and Chen, Y.(2017) Quantifying the Body and Caring for the Mind: Self-Tracking in Multiple Sclerosis. *Proceedings of the 2017 CHI Conference on Human Factors in Computing Systems.*

Babbage, D., Kessel, K., Drown, J., Thomas, S., Sezier, A., Thomas, P. and Kersten, P. (2019) MS Energize: Field trial of an app for self-management of fatigue for people with multiple sclerosis. I*nternet Interventions* v18, 100291.

Baltaxe, E., Czypionka, T., Kraus, M., Reiss, M., Askildsen, JE., Grenkovic, R., Lindén, TS., Pitter, JG., Rutten-van Molken, M., Solans, O., Stokes, J., Struckmann, V., Roca, J. and Cano, I. (2019) Digital Health Transformation of Integrated Care in Europe: Overarching Analysis of 17 Integrated Care Programs. *J Med Internet Res*, Sep 26;21(9).

Bandura, A. (1997) *Self-Efficacy: The Exercise of Control.* San Francisco, CA: W.H. Freeman and Company.

Bartnik, E. and Chalmers, R. (2007) It's about more than money: Local area co-ordination supporting people with disabilities. *Research highlights in social work: Co-production and Personalisation in social care. Changing relationships in the provision of social care.* 49, 19-38.

Bethancourt, H. J., Rosenberg, D. E., Beatty, T. and Arterburn, D. E. (2014) Barriers to and facilitators of physical activity program use among older adults. *Clin. Med. Res.* 12, 10–20.

Brett, J., Staniszewska, S., Mockford, C., Seers, K., Herron-Marx, S. and Bayliss, H. (2010) *The PIRICOM Study: A Systematic Review of the Conceptualisation, Measurement, Impact and Outcomes of Patients and Public Involvement in Health and Social Care Research.* Coventry, UK, University of Warwick, http://wrap.warwick.ac.uk/47235/

Bodenheimer, T. (2002) Patient self-management of chronic disease in primary care. *JAMA* 288:2469.

Bove, R.M., Rush, G., Zhao, C., Rowles, W., Garcha, P., Morrissey, J., Schembri, A., Alailima, T., Langdon, D., Possin, K., Gazzaley, A., Feinstein, A., Anguera, J. (2019) A Videogame-Based Digital Therapeutic to Improve Processing Speed in People with Multiple Sclerosis: A Feasibility Study. *Neurol Ther,* Jun 8(1):135-145.

Brandsen, T. and M. Honingh. (2018) Definitions of Co-production and Co-creation. In *Co-production and Co-creation. Engaging Citizens in Public Services,* edited by T. Brandsen, T. Steen, and B. Verschuere, 9–17. New York and London: Routledge.

Cameron, J. E., Voth, J., Jaglal, S. B., Guilcher, S. J. T., Hawker, G., and Salbach, N. M. (2018) In this together: social identification predicts health outcomes (via self-efficacy) in a chronic disease self-management program. *Soc. Sci. Med,* 208, 172–179.

Coulter, A. and Ellins, J. (2007) Effectiveness of strategies for informing, educating, and involving patients. *BMJ*, Jul 07;335(7609):24-27.

Cripps, M. and Scarborough, H. (2022) Making Digital Health "Solutions" Sustainable in Healthcare Systems: A Practitioner Perspective. *Frontiers in Digital Health (4).*

Davies, N.J. (2010) Improving self-management for patients with long-term conditions. *Nursing Standard* 24(25):49-56.

Dendere, R., Slade, C., Burton-Jones, A., Sullivan, C, Staib, A. and Janda, M. (2019) Patient Portals Facilitating Engagement with inpatient Electronic Medical Records: A Systematic Review. *J Med Internet Research.* Apr 11:21(4).

Department for Health (2010) A vision for Adult Social Care: Capable communities and active citizens. White Paper, London: The Stationary Office.

Department for Health and Social Care (2020) Integration and Innovation: working together to improve health and social care for all. White Paper, London: The Stationary Office.

Dixit, S. and Tedla, J.S. (2019) Effectiveness of robotics in improving upper extremity functions among people with neurological dysfunction: a systematic review. *Int J Neurosci* 129(4) 369 – 383.

Domecq, J.P., Prutsky, G., Elraiyah, T. et al. (2014) Patient engagement in research: a systematic review. *BMC Health Serv Res* 14, 89. https://doi.org/10.1186/1472-6963-14-89

Druce, K. L., Dixon, W. G., and McBeth, J. (2019) Maximizing Engagement in Mobile Health Studies: Lessons Learned and Future Directions. *Rheumatic diseases clinics of North America,* 45(2), 159–172.

Dunn,P. and Hazzard, E.(2019) Technology approaches to digital health literacy, *International Journal of Cardiology,* 293, 294-296.

Durose, C., Mangan, C., Needham, C., and Rees, J. (2014) Evaluating co-production: pragmatic approaches to building the evidence base. Paper presented to Political Studies Association conference 2014.

Duscha, B. D., Piner, L. W., Patel, M. P., Crawford, L. E., Jones, W. S., Patel, M. R., et al. (2018) Effects of a 12-week mhealth program on functional capacity and physical activity in patients with peripheral artery disease. *Am. J. Cardiol.* 122, 879–884.

Elg, M., Engstrom, J., Witell, L. and Poksinska, B. (2012) Co-Creation and Learning in Health-Care Service Development. *Journal of Service Management,* (23, 3), 328–343.

Farr, M. (2018) Power dynamics and collaborative mechanisms in co-production and co-design processes. *Critical Social Policy* (38, 4), 623-644.

Farmer, A., Williams, V., Velardo, C., Shah, S.A., Yu, L., Rutter, H., Jones, L., Williams, N., Heneghan, C., Price, J., Hardinge, M. and Tarassenko, L. (2017) Self-Management Support Using a Digital Health System Compared With Usual Care for Chronic Obstructive Pulmonary Disease: Randomized Controlled Trial. *J Med Internet Res,* 19(5):e144.

Fergusson, D., Monfaredi, Z., Pussegoda, K. et al. (2018) The prevalence of patient engagement in published trials: a systematic review. *Res Involv Engagem,* 4, 17.

Gallagher, R., Donoghue, J., Chenoweth, L., and Stein-Parbury, J. (2008) Self-management in older patients with chronic illness. *Int. J. Nurs. Pract.* Oct 14(5):373-82.

Greenhalgh, T., Jackson, C., Shaw, S., and Janamian, T. (2016) Achieving Research Impact Through Co-creation in Community-Based Health Services: Literature Review and Case Study. The Milbank Quarterly, 94(2) 392-429.

Greenhalgh, T., Wherton, J., Papoutsi, C., Lynch, J., Hughes, G., A'Court, C., Hinder, S., Fahy, N., Procter, R. and Shaw, S. (2017) Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. *J Med Internet Res,* 19(11).

Gopal, G., Suter-Crazzolara, C., Toldo, L. and Eberhardt, W. (2019) Digital transformation in healthcare - architectures of present and future information technologies. *Clin Chem Lab Med.* 57:328–35.

Geurts, E., Van Geel, F., Feys, P. and Coninx, K. (2019) WalkWithMe: Personalized Goal Setting and Coaching for Walking in People with Multiple Sclerosis. *Proceedings of the 27th ACM Conference on User Modeling, Adaptation and Personalization - UMAP '19* (Larnaca, Cyprus), 52–60.

Haase, R., Wunderlich, M., Dillenseger, A., Kern, R., Akgun, K. and Ziemssen, T. (2018) Improving multiple sclerosis management and collecting safety information in the real world: the MSDS3D software approach. *Expert Opin Drug Saf.* 17:369–78.

Hatzidimitriadou, E., Mantovani, N., and Keating F. (2012) *Evaluation of co-production processes in a community-based mental health project in Wandsworth.* London: Kingston University, St. Georges University of London.

Henderson, C., Knapp, M., Fernandez, J. et al. (2013) Cost effectiveness of telehealth for patients with long term conditions. *BMJ,* 346:f1035.

Huckman, R. and Stern, A. (2018) Why Apps for Managing Chronic Disease Haven't Been Widely Used, and How to Fix It. *Harvard Business Review,* April 4.

Incisive Health International (2018) *Taking the pulse of eHealth in the EU An analysis of public attitudes to eHealth issues in Austria, Bulgaria, Estonia, France, Germany, Italy, and the UK*. Brussels: Incisive Health.

Irizarry, T., DeVito Dabbs, A. and Curran, C.R. (2015) Patient Portals and Patient Engagement: A State of the Science Review. *J Med Internet Res*. Jun 23;17(6).

Jongen, P.J., Sinnige, L.G., van Geel, B.M., Verheul, F., Verhagen, W.I., van der Kruijk, R.A., et al. (2016) The interactive web-based program MSmonitor for self-management and multidisciplinary care in multiple sclerosis: utilization and valuation by patients. *Patient Prefer Adherence,* 10:243-250.

Jongen, P.J., Sinnige, L.G., van Geel, B.M., Verheul, F., Verhagen, W.I., van der Kruijk, R.A., et al. (2015) The interactive web-based program MSmonitor for self-management and multidisciplinary care in multiple sclerosis: concept, content, and pilot results. *Patient Prefer Adherence,* 9:1741-175.

Jongen, P.J., ter Veen, G., Lemmens, W., Donders, R., van Noort, E. and Zeinstra E. (2020) The Interactive Web-Based Program MSmonitor for Self-Management and Multidisciplinary Care in Persons With Multiple Sclerosis: Quasi-Experimental Study of Short-Term Effects on Patient Empowerment *J Med Internet Res,* 22(3):e14297

Larbi, D., Randine, P., Årsand, E., Antypas, K., Bradway, M. and Gabarron, E. (2020) Methods and Evaluation Criteria for Apps and Digital Interventions for Diabetes Self-Management: Systematic Review. *J Med Internet Res*;22(7).

Lauren, N., Fielding, K. S., Smith, L. and Louis, W. R. (2016) You did, so you can and you will: self-efficacy as a mediator of spill over from easy to more difficult pro-environmental behaviour. *J. Environ. Psychol*. 48, 191–199.

Lavorgna, L., Brigo, F., Moccia, M., Leocani, L., Lanzillo, R., Clerico, M., Abbadessa, G., Schmierer,K., Solaro,C., Prosperini, L., Tedeschi, G., Giovannoni, G., and Bonavita, S. (2018) e-Health and multiple sclerosis: An update *Multiple Sclerosis Journal,* 24(13) 1657–1664.

Leigh, S., Daly, R., Stevens, S., et al (2021) Web-based internet searches for digital health products in the United Kingdom before and during the COVID-19 pandemic: a time-series analysis using app libraries from the Organisation for the Review of Care and Health Applications (ORCHA). *BMJ Open,* 11:e053891.

Lenferink, A., van der Palen, J., van der Valk, P., Cafarella, P., van Veen, A., Quinn, S., et al. (2017) Effects of self-management action plans for COPD patients with comorbidities on health status and self-efficacy. *Eur. Respir.* Soc. 50.

Leone, R. P., Walker, C. A., Curry, L. C. and Agee, E. J. (2012) Application of a Marketing Concept to Patient-Centered Care: Co-Producing Health with Heart Failure Patients. *Online Journal of Issues in Nursing,* (17, 2)

Long, J. C., Cunningham, F.C. and Braithwaite, J. (2013) Bridges brokers and boundary spanners in collaborative networks: a systematic review. *BMC Health Serv Res.* 13:158.

Lorig, K., Ritter, P. L., Villa, F. J., and Armas, J. (2009) Community-based peer-led diabetes self-management: a randomized trial. *Diabetes Educ*. 35, 641–652.

Maguire, D., Evans, H., Honeyman, M. and Omojomolo, D. (2018) *Digital change in health and social care*. London: The King's Fund.

Marmot, L. (2010) *Fair Society: Healthy Lives.* London: Institute of Health Equity.

Marziniak, M., Brichetto, G., Feys, P., Meyding-Lamadé, U., Vernon, K. and Meuth, S.G. (2018)
The Use of Digital and Remote Communication Technologies as a Tool for Multiple Sclerosis Management: Narrative Review. *JMIR Rehabil Assist Technol,* 5(1):e5.

Matthews, P, M., Block, V, J. and Leocani, L.(2020) E-health and multiple sclerosis, *Current Opinion Neurology* 33:271 – 276.

McCabe, C., McCann, M. and Brady, A.M. (2017) Computer and mobile technology interventions for self-management in chronic obstructive pulmonary disease. *Cochrane Database of Systematic Reviews,* 5 : CD011425.

Michie, S. and Johnston, M. (2012) Theories and techniques of behaviour change: developing a cumulative science of behaviour change. *Health Psychol Rev;* 6: 1–6.

Miles, M.B., Huberman, M., and Saldana, J. (2014) Qualitative Data Analysis: *A Methods Sourcebook and The Coding Manual for Qualitative Researchers.* Thousand Oaks, CA: SAGE.

Mockford, C., Staniszewska, S., Griffiths, F., Herron-Marx, S. (2012) The impact of patient and public involvement on UK NHS health care: a systematic review. *Int J Qual Health Care*., 24 (1): 28-38.

Morgan, H. M., Entwistle, V. A., Cribb, A., Christmas, S., Owens, J. and Skea, Z. C. (2017). We need to talk about purpose: a critical interpretive synthesis of health and social care professionals' approaches to self-management support for people with long-term conditions. *Heal Expect.* 20, 243–259.

Morton, K., Dennison, L,. May, C., Murray, E,. Little, P,. McManus, R,J, and Yardley, L.(2017)
Using digital interventions for self-management of chronic physical health conditions: A meta-ethnography review of published studies, *Patient Education and Counseling,*100(4) 616-635

Motl, R.W. and Dlugonski, D. (2011) Increasing physical activity in multiple sclerosis using a behavioural intervention. *Behav Med* 37:125 – 131.

Nilsen, E.S., Myrhaug, H.T., Johansen, M., Oliver, S. and Oxman, A.D. (2006) Methods of consumer involvement in developing healthcare policy and research, clinical practice guidelines and patient information material. *Cochrane Database Syst Rev.*, 3: CD004563.

ONS (2019) *Exploring the Uk's digital divide*.
Accessed Nov 2021 https://www.ons.gov.uk/peoplepopulationandcommunity/householdcharacteristics/homeinternetandsocialmediausage/articles/exploringtheuksdigitaldivide/2019-03-04

Ostrom, E., Parks, R., Whitaker, G.P. and Percy S.L. (1978) The Public Service Production Process: A Framework for analysing Police Services. *Policy Studies Journal*,7, 813-842.

Owen, T., Pearson, J., Thimbleby, H. W. and Buchanan, G. (2015) ConCap: Designing to Empower Individual Reflection on Chronic Conditions using Mobile Apps. In: MobileHCI '15 Proceedings of the 17th International Conference on Human-Computer Interaction with Mobile Devices and Services. (105-114). New York, NY: ACM.

Panagioti, M., Richardson, G., Small, N., Murray, E., Rogers, A., Kennedy, A., Newman, S. and Bowes, P. (2014) Self-management support interventions to reduce health care utilisation without compromising outcomes: a systematic review and meta-analysis. *BMC Health Services Research* 14:356.

Perro J.(2018) Mobile apps: what's a good retention rate? https://info.localytics.com/blog/mobile-apps-whats-a-good-retention-rate : Accessed March 2022.

Powers, M. A., Bardsley, J., Cypress, M., Duker, P., Funnell, M. M.and Fischl, A. H. (2017) Diabetes self-management education and support in type 2 diabetes. *Diabetes Educ.* 43, 40–53.

Paul, L., Renfrew, L., Freeman, J., et al. (2019) Web-based physiotherapy for people affected by multiple sclerosis: a single blind, randomized controlled feasibility study. *Clin Rehabil* 33:473 – 484.

Reeves, D., Blickem, C., Vassilev, I., Brooks, H., Kennedy, A., Richardson, G., et al. (2014) The Contribution of social networks to the health and self-management of patients with long-term conditions: a longitudinal study. *PLoS One* Jun 2;9(6):e98340.

Richie, J. and Lewis, J. (2003) Generalising from qualitative research. In J. Lewis and J. Richie (Eds) *Qualitative Research and Practice: A guide for Social Science Students and Researchers,* Sage.

Robert, G., Donetto, S. and Williams, O. (2020) Co-designing Healthcare Services with Patients. In E. Loeffler, and T. Bovaird (Eds.), *The Palgrave Handbook of Co-Production of Public Services and Outcomes* Palgrave Macmillan.

Ross, C., and Mirowsky, J. (2010). *Why Education is the Key to Socioeconomic Differentials in Health*. Nashville, TN: Vanderbilt University Press.

Sarkar, U., Fisher, L., and Schillinger, D. (2006) Is self-efficacy associated with diabetes self-management across race/ethnicity and health literacy? *Diabetes Care* 29, 823–829.

Schwarzer, R., and Jerusalem, M. (1995) Generalized Self-Efficacy scale. In J. Weinman, S. Wright, and M. Johnston (Eds). *Measures in health psychology: A user's portfolio. Causal and control beliefs* (35-37). Windsor, UK.

Scott, I, A., Scuffam, P., Gupta, D., Harch, T., Borchi, J. and Brent, R. (2020) Going digital: a narrative overview of the effects, quality and utility of mobile apps in chronic disease self-management *Australian Health Review,* 2020, 44, 62–82.

Setiawan, I.M.A., Zhou, L., Alfikri, Z., Saptono, A., Fairman, A.D., Dicianno, B.E. and Parmanto, B. (2019) An Adaptive Mobile Health System to Support Self-Management for Persons With Chronic Conditions and Disabilities: Usability and Feasibility Studies *JMIR Form Res*;3(2):e12982.

Seyfang, G. (2004) Time banks; rewarding community self-help in the inner city? *Community Development Journal* 39:1, 62-7.

Siegal, J. (2016) Is Pokemon Go already dying? Available at: https://bgr.com/2016/08/23/pokemon-go-daily-active-users/ Accessed May 2022.

Slay, J. and Stephens, L. (2013). *Co-Production in Mental Health: A Literature Review*. London: New Economics Foundation.

Smith, B., and Magnani, J. W. (2019). New technologies, new disparities: The intersection of electronic health and digital health literacy. *International journal of cardiology,* 292, 280–282.

Soelberg Sorensen, P., Giovannoni, G., Montalban, X., Thalheim, C., Zaratin, P. and Comi, G. (2018) The multiple sclerosis care unit. *Mult Scler.* 25(5):627-636.

Strecher, V. J., McEvoy DeVellis, B., Becker, M. H., and Rosenstock, I. M. (1986). The role of self-efficacy in achieving health behaviour change. *Heal Educ. Behav.* 13, 73–92.

Tallner, A., Pfeifer, K. and Maurer, M. (2016) Web-based interventions in multiple sclerosis: the potential of tele-rehabilitation. *Ther Adv Neurol Disord.* 9:327-335.

Tesch, R (1990) *Qualitative research: Analysis types and software.* Routledge, New York.

van Beek, J.J.W., van Wegen, E.E.H., Bol, C.D., et al. (2019) Tablet App Based Dexterity Training in Multiple Sclerosis (TAD-MS): research protocol of a randomized controlled trial. *Front Neurol* 10:61.

van Kessel, K., Wouldes, T. and Moss-Morris, R. (2016) A New Zealand pilot randomized controlled trial of a web-based interactive self-management programme (MSInvigor8) with and without E-Mail support for the treatment of multiple sclerosis fatigue. *Clin Rehabil* 30:454 – 462.

Vasilica, C. M., Brettle, A., and Ormandy, P. (2020) A Co-Designed Social Media Intervention to Satisfy Information Needs and Improve Outcomes of Patients With Chronic Kidney Disease: Longitudinal Study. *JMIR formative research,* 4(1), e13207. https://doi.org/10.2196/13207

Vennik, D.,van de Bovenkamp, H., Putters, K. and Grit, K. (2015) Co-production in healthcare: rhetoric and practice. *International Review of Administrative Sciences* Vol. 82(1) 150–168.

Voigt, I., Benedict, M., Susky, M., Scheplitz, T., Frankowitz, S., Kern, R., Müller, O., Schlieter, H. and Ziemssen, T. (2020) A Digital Patient Portal for Patients with Multiple Sclerosis. *Frontiers in Neurology*, 11,400.

Wagner, E. H., Austin, B. T., Davis, C., Hindmarsh, M., Schaefer, J. and Bonomi, A. (2001) Improving chronic illness care: translating evidence into action. *Health Aff.* 20, 64–78

Wendrich, K., van Oirschot, P., Martens, M. B., Heerings, M., Jongen, P. J., and Krabbenborg, L. (2019). Toward Digital Self-monitoring of Multiple Sclerosis: Investigating First Experiences, Needs, and Wishes of People with MS. *International journal of MS care*, 21(6), 282–291.

Wicks, P., and Chiauzzi, E. (2015) 'Trust but verify'–five approaches to ensure safe medical apps. *BMC Med*; 13:205.

Wulfovich, S., Fiordelli, M., Rivas, H., Concepcion, W. and Wac, K. (2019) I Must Try Harder": Design Implications for Mobile Apps and Wearables Contributing to Self-Efficacy of Patients with Chronic Conditions, *Frontiers in Psychology,* 10, 2388.

Yi, J.Y., Kim, Y., Cho, Y.M. and Kim, H. (2018). Self-management of Chronic Conditions Using mHealth Interventions in Korea: A Systematic Review. *Healthcare informatics research,* 24(3), 187–197.

Ziemssen, T. (2009) Multiple sclerosis beyond EDSS: depression and fatigue. *J Neurol Sci.* 277:S37–41.

Ziemssen, T. and Thomas, K. (2017) Treatment optimization in multiple sclerosis: how do we apply emerging evidence? *Expert Rev Clin Immunol* 13:509–11.

Appendix 2

Design re-specifications prioritised by PwMS

QUESTION	ALL RESPONDENT’S	PATIENTS ONLY
Q4. Free text space to add notes. e.g. Top 5 questions to say when with doctor to avoid door handle conversations when the appointment is over and the patient is about it leave bring up an issue	9.8	10.0
Q8. Provide an MS specific survey (including things like; spam triggers, continence, mobility, etc)	9.7	9.7
Q12. Continence option in events	9.4	9.3
Q13. Spasm triggers option in events	9.1	9.0
Q28. Allowing users to input their own observations, such as with a text box	9.0	9.2
Q2. Hovering on icons shows description text so that what they mean is clear	8.8	8.8
Q18. Tracking of mobility ‘equipment’ used. e.g. using a walking stick or not to help move	8.8	8.3
Q14. Change colour options to Red, Amber, Green Traffic light system rather than yellow/purple/grey so it’s easier to understand	8.7	8.3
Q9. Option to duplicate entries from previous survey answers if no change (for example on a good day duplicate previous answers)	8.3	8.0

REQUIREMENTS/NOTES	DAY DEV/CONFIG	IN SCOPE?
Already in events and wellbeing reports functionality - Training need(video). Can implement quick links from dashboard		yes
	5days	
Survey data template to be completed + build time, icons, clinical verification	PER SURVEY icons : 3days clinical Verification: TBC Build, test, deploy: 1 day	yes
Scope to include in health section	1 day	yes
Scope to include in health section	1 day	yes
Already in place. Free text entry at the end of each input	0 days	n/a
Fix to be implemented on events tiles. Can add info on surveys as default	0.5 days	yes
Add ms as a condition to events with options for treatment to include mobility aids	use existng hierachy logic: 1 day New element: 5 days	yes
Colour change	1 day	yes
Not recommended (statistical impact)	0	no

QUESTION	ALL RESPONDENT'S	PATIENTS ONLY
Q27. Key words search for MS related actions and symptoms	8.3	8.7
Q21. Option to skip fields if not relevant or desired	8.2	9.3
Q26. Links to other relevant articles	8.2	8.8
Q17. Sliders need to be clearer with explanation of what's being asked	8.1	7.5
Q3. Entered medications can be seen on the home screen	8.0	7.5
Q23. Indicate what a good/ bad day is (to give base line)	8.0	7.8
Q22. Option to integrate with ""sympton"" tracker app	7.9	8.7
Q5. Add an option to Duplicate input from previous days	7.8	7.8
Q11. Add a way of duplicating events without inputting data when there is no change	7.8	8.0
Q24. Be able to see a 2 week daily base line	7.7	7.5
Q29. Ability to email and/or print a pdf of reports	7.6	8.0

REQUIREMENTS/NOTES	DAY DEV/CONFIG	IN SCOPE?
Pick up by content task	See content additions	yes
survey config	1 day	yes
see content additons		yes
survey config	0.5 day	yes
custom input widget/ fields	2 days	yes
training needs		
Coverage across IOS/Android using google fit/fitbit	0	no
not recommended(statistical impact)		n/a
not recommended(statistical impact)		n/a
already available in custom results	0days	yes
already avalible. Download pdf, then email	0days	yes

QUESTION	ALL RESPONDENT’S	PATIENTS ONLY
Q30. Ability to Intergrate with more wearable/connected medical devices, e.g. smart watch	7.6	8.0
Q10. Preference to have to slide one direction (always lowest score on one side and highest on the other) rather than have to figure out each separately	7.4	6.5
Q20. Clarify what colours on scales needs more description/ explanation	7.4	6.5
Q16. Inputting an estimation needs to be clear and consistent - further indicators and explanation	6.7	6.2
Q19. Integrate with other platforms such as ‘Park Run’ website times	6.7	6.5
Q15. Add an option for Caffine intake	5.7	4.8
Q25. Not to have a continuous line on the graph (I.E. assumes some data that is not evident)	5.7	4.7
Q6. pop up to explain for Who has access to this information	5.2	5.7
Q7. pop up to explain for What is the relevance on NI number	5.1	5.5

REQUIREMENTS/NOTES	DAY DEV/CONFIG	IN SCOPE?
Coverage across IOS/Android using google fit/fitbit	see content additions	yes
not recommended (statistical impact)	1 day	yes
		yes
Is this wellbeing results or events?	0.5 day	yes
Self report and evaluation	2 days	yes
Coverage across IOS/Android using google fit/fitbit		no
consider in survey structure(daily lifestyle, vs. weekly/monthly wellbeing tracking	0	n/a
graphical interface and logic development		n/a
privacy section in profile demostrates access matrix and editing permissons	0 days	yes
personal identifier not a required filed. Used for social system integration across the platform	0 days	yes

Appendix 3

Participant Information Sheet

Study Title:
An App for the self-management of long term conditions in Salford, using Multiple Sclerosis as an exemplar.

Short Title:
Salford Multiple Sclerosis (MS) App study.

Principal Investigator: Dr David Rog

1. Introduction

You are being invited to take part in a study based at Salford Royal NHS Foundation Trust. Before you decide it is important for you to understand why this research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

2. Why have I been invited to take part?

You are being invited to take part in this study because you are a person with Multiple Sclerosis, living in Salford or registered with a Salford GP. You may have already expressed an interest in using digital enablers to improve healthcare.

3. What is the purpose of the research?

The purpose of this research is to investigate the acceptability and use of the MS app to promote self-management, by people with MS, of their healthcare, between their clinic appointments. By creating a digital profile of the symptoms, you have, your medications, levels of activity and other health information, we will be able to match you with specific relevant health information provided by the MS Trust. We are keen to understand how this is best presented to you to maximise its benefit and you will have the opportunity to rate this and the App in general. We aim to demonstrate how the App can make your appointments with healthcare professionals more efficient, impactful and meaningful to you.

4. What will happen if I take part?

You will receive the invitation/ initial information letter from a member of the study team, usually the MS Research Assistant. It will take about 10 minutes to read this form and you will be given at least 24 hours to consider whether you wish to participate. The study team will then be in touch and you will then have the opportunity to ask questions from the study team on a telephone or Microsoft Teams. If you wish to participate in the study, the study team will read out the consent form, word for word, and ask you to confirm that you agree with each clause and record your answer. This will take approximately 45 minutes. You will then receive further assistance as to how to access the MS web app from your device and browser and how to configure it with details of your MS, with support from the MS Research Assistant via MS Teams. The MS Research Assistant will also ask you a series of questions about how you usually manage your health. This may take up to an hour. The MS app contains a series of "sliders'' that allow you to rate your MS symptoms and general health, as regularly as you feel is necessary. In the 2-week run in period, we would like you to record how you feel on a "good", "bad" and "average" day on at least one occasion each, if you experience these, so that we are able to assess the variability in your MS and how each component, for example sleep quality, is related to others, eg nerve pain and fatigue. This may take up to 30 minutes. During the 6 month period of the study, we would like you to use these sliders to rate your health, ideally on a weekly basis and also rate the information that is sent to you. You will have the opportunity to decline or postpone doing so if inconvenient. At the beginning of the study we will send you a link to a questionnaire, by email with a series of questions about how you usually manage your health. We will send the same questionnaire again half-way through and at the end of the study period, to see if using the MS app has made a difference. At the end of the study period, we would like you to participate in a group interview online via Microsoft Teams which will last approximately 2 hours. In total we would expect that you would be involved for around 20 hours, over around a 6 month period, contributing your health data, but you may find you spend additional time accessing relevant information about MS, if you find it beneficial.

5. Do I have to take part?

No, taking part is voluntary and it is up to you to decide whether or not to take part. Any help you give is very much appreciated. If you decide to take part you are free to withdraw at any time without giving a reason. A decision to withdraw at any time will not affect the standard of any care you receive. If you decide not to take part you do not have to give a reason.

6. What are the possible benefits of taking part?

The study may not have a direct benefit to you but will help our understanding of how feasible it is to use an app routinely, to improve healthcare and outcomes for people with MS and other long-term conditions.

At the end of the study, information that you contribute to the app will be summarised and scanned into your Salford Royal NHS Foundation Trust electronic patient record, so will be available for your clinical team, in the future, if required.

7. What are the possible disadvantages and risks of taking part?

We have developed the content of the app with people with MS and have a patient lead as a core part of our study team to ensure that the content is relevant and appropriate to people with MS.

However, there is potential that clinical risks could be identified when we analyse the data you provide, for example if you indicated that your mood was low. These would be referred immediately to the clinical team at Salford Royal Hospital MS Clinic, for their attention.

There is potential that you might be upset during the study interview. If this were to occur, then the research assistant who attends the interview as an observer will attend to this in the first instance and refer to the clinical team or signpost you to information sources such as the MS Trust, as appropriate.

8.

a) How will we use information about you?

The Salford Royal study team will need to use information from your medical records about your MS for this research project.

This information will include:
Your information held by the hospital:

- Initials
- NHS number
- Name
- Age
- Contact details
(including the first three letters of your postcode)
- Type of MS
- Date of diagnosis
- disability level
- employment status
- level of education
- ethnicity
- information about your local area from your postcode

Your information held by the App's Platform, will include:

In order to use the platform

- First name
- Surname
- Email address
- Gender
- User name
- Password

Optional data that you may choose to add on the App's platform:

- Lifestyle
- Activity level
- Exercise level
- Fitness level
- Sport participation
- Sleep
- Nutrition
- Smoking
- Physical ability
- Mental ability
- Social ability
- Carer Information
- Dietary preferences

Interests

Your information held by the University of Salford research team (which does not identify you):

- Gender
- Ethnicity
- Disability level
- Age
- Employment status
- Education
- Receipt of Tablet device Yes / No

People will use this information to do the research or to check your records to make sure that the research is being done properly.

The questionnaires and interview part of this project will be undertaken by a research team at the University of Salford. Invitations to participate in questionnaires or participate in group interviews will be sent by the Salford Royal study team rather than the University of Salford research team, and so they will not be able to see your name or contact details. Your data will have a code number instead and no information that can identify you will be stored or viewed by anyone outside of your routine clinical team.

The staff at the technology partner (providers of the App's platform being used in this study) will not have access to view any personal data about you unless you explicitly allow it.

We will keep all information about you on secure, password protected servers and devices only.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

b) What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

c) Where can you find out more about how your information is used?

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients/

- our leaflet available from https://www.ncaresearch.org.uk/patients-public/

By asking one of the research team (details below)

- by contacting the Northern Care Alliance NHS Group Data Protection Officer DataProtection.Officer@srft.nhs.uk

- by viewing the Sponsor's privacy link http://srft.nhs.uk/for-patients/information/privacy-notice-adults/

9. Expenses and payments?

We are unable to pay you for participating in this study. However, no travel is required as all study procedures will be undertaken over MS teams or the telephone.

10. What will happen to the results of the research study?

The final outcomes from the study will be communicated via presentations in scientific meetings and by peer reviewed publications. Any data or quotes you provide which are used in publications will be anonymised and not attributable to you. We will aim to publish the results approximately 12 months after completion of the study. These can be shared with participants if they wish.

11. Who is organising and funding the research?

The research is organised by, Salford Royal NHS Foundation Trust and the University of Salford. The research is funded by Salford Clinical Commissioning Group and management oversight (Sponsorship) is provided by Salford Royal NHS Foundation Trust.

12. Who has reviewed this study?

We can confirm that the study has been reviewed and approved by an appropriate NHS Research Ethics Committee, (Research Ethics Committees [insert REC name here). The University of Salford Ethics Committee has also reviewed and approved the study.

13. What if there is a problem?

If taking part in the study harms you, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you have a concern about any aspect of the way you have been approached or treated during this study, you should speak to the researchers who will do their best to answer your questions (see contact details below).

If you have any complaints about the treatment you have received as part of this study, you can contact the hospital PALs (Patient Advise and Liaison Services) team:

Patient Advice and Liaison Service
Salford Royal NHS Foundation Trust
Stott Lane, Salford M6 8HD
Telephone: 0161 206 2003

Contact Names and Details for Further Information:
Dr David Rog, Consultant Neurologist
Telephone: 0161206 0534
Email: Neuroresearch.nurse@srft.nhs.uk

Study Coordinator: Stephanie Mitchell
Telephone: 0161206 4406
Email: Stephanie.mitchell@srft.nhs.uk

If you have any questions about this research, please write to us or call us on 01612064406.

Thank you for taking the time to read this information sheet.

Participant Informed Consent Form

Participant ID: ______________________________

Study Title: An App for the self-management of long-term conditions in Salford, using Multiple Sclerosis as an exemplar.

Principal Investigator: Dr David Rog

	PLEASE INTIAL BOX
1. I confirm that I have read the information sheet dated ....(version....................) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected	
3. I understand that if I withdraw from the study, data collected prior to me leaving, will not be removed from the study	
4. I understand that the information collected from me may be used to support other research in the future and may be shared anonymously with other researchers.	
5. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records	

Name of Participant: ____

Date: ____

Signature: ____

Name of Consent: ____

Date: ____

Signature: ____

	PLEASE INTIAL BOX
6. I understand that any information used from the online App will be anonymous and not attributable to me	
7. I agree to participate in a focus group meeting with other users at the end of the study to share my experience of using the App	
8. I understand that the focus group meeting will be recorded and the information will be used to inform the study	
9. I understand that any information collected from the focus group will be anonymous and not be attributable to me	
10. I understand that any disclosure of criminal activity or other disclosures requiring action will have to be reported to the appropriate authorities	
11. I agree to take part in the above study	

Appendix 4

General Self-Efficacy Scale (GSE)

About

This scale is a self-report measure of self-efficacy.

Items

10

Validity

The General Self-Efficacy Scale is correlated to emotion, optimism, work satifaction. Negative coefficients were found for depression, stress, health, complaints, burnout, and anxiety.

Scoring

	Not at all true	Hardly True	Moderately True	Exactly True
All questions	1	2	3	4

The total score is calculated by finding the sum of the all items. For the GSE, the total score ranges between 10 and 40, with a higher score indicating more self-efficacy.

References

Schwarzer, R., Jerusalum, M. **Generalized Self-Efficacy Scale.** In J. Weinman, S. Wright, & M. Johnston, Measures in health psycology: A user’s portfolio. Causal and control beliefs (pp. 35-37). Windsor, UK: NFER-NELSON.

General Self-Efficacy Scale (GSE)

	PLEASE TICK BOX			
	Not at all true	Hardly true	Moderately true	Exactly true
1. I can always manage to solve difficult problems if I try hard enough.				
2. If someone opposes me, I can find the means and ways to get what I want.				
3. It is easy for me to stick to my aims and accomplish my goals.				
4. I am confident that I could deal efficiently with unexpected events.				
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.				
6. I can solve most problems if I invest the necessary effort.				
7. I can remain calm when facing difficulties because I can rely on my coping abilities.				
8. When I am confronted with a problem, I can usually find several solutions.				
9. If I am in trouble, I can usually think of a solution				
10. I can usually handle whatever comes my way.				

University of
Salford
MANCHESTER