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Optimising the Depression
Pathway Enabled by Novel Digital
Assessment Technology

**FINAL
EVALUATION
REPORT**

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1. Executive summary

Introduction and methodology:

In the United Kingdom, one in six people aged 18 or over report symptoms of a common mental disorder such as anxiety or depression. Despite the growing interest in the quality of care for depression, there has been little evaluation of this in primary care settings. Digital technology, including applications (apps) for mobile phones and tablets are being created to complement clinical care and more than 13 web applications and 35 smartphone apps are available in the NHS for depression, anxiety or stress.

This report details findings from the implementation and evaluation of a new service, seeking to optimise the current depression care pathway in a primary care setting. A 'walk-in' service was piloted for one year at two GP services (a single primary care network) using a multi-disciplinary team of health/social care professionals with specialist knowledge of mental health and wellbeing providing a range of therapy options. Built into the service was the use of a novel digital technology, i-spero, designed to assist service users with managing depression and supporting professionals in clinical decision making and management.

The service evaluation followed a mixed methods, observational feasibility study design, using an evidence integration triangle implementation research approach to identify changes in context regarding implementation and resource use, who and what was affected and how, the effects on user outcomes and experiences, plus the experience of healthcare professionals. The evaluation follows the NICE evidence standards framework for digital health technologies. The study comprised an intervention group of service users (n=109) who received six months' care for low mood, depression and/or anxiety from the new service, compared to a standard care group (n=48).

Specifically, the evaluation set out to answer the following questions:

- What impact has the systematic pathway had on service user experience and outcomes?
- What are the components of the care delivery model ('active/successful ingredients') that are really making a difference?
- What are the influencing contextual factors and how have they affected implementation and outcomes?
- What changes to the use of resources and activity have occurred and how have they impacted costs?
- What could be improved, replicated and sustained?

Service user experience and outcomes of the new care pathway

- The walk-in clinic was rated highly with 95.5% happy with the care received. Services exceeded expectations for 56.5% of service users in the intervention group compared to 20.5% in the standard care group ($p < 0.001$).
- Services users were happy to use the i-spero technology to guide their care and management, found it easy to use and 87% indicated that they would use the technology again if it was offered to them.

"100%. Yeah, I think it's much much better than any other service I've had around mental health." (SU59)

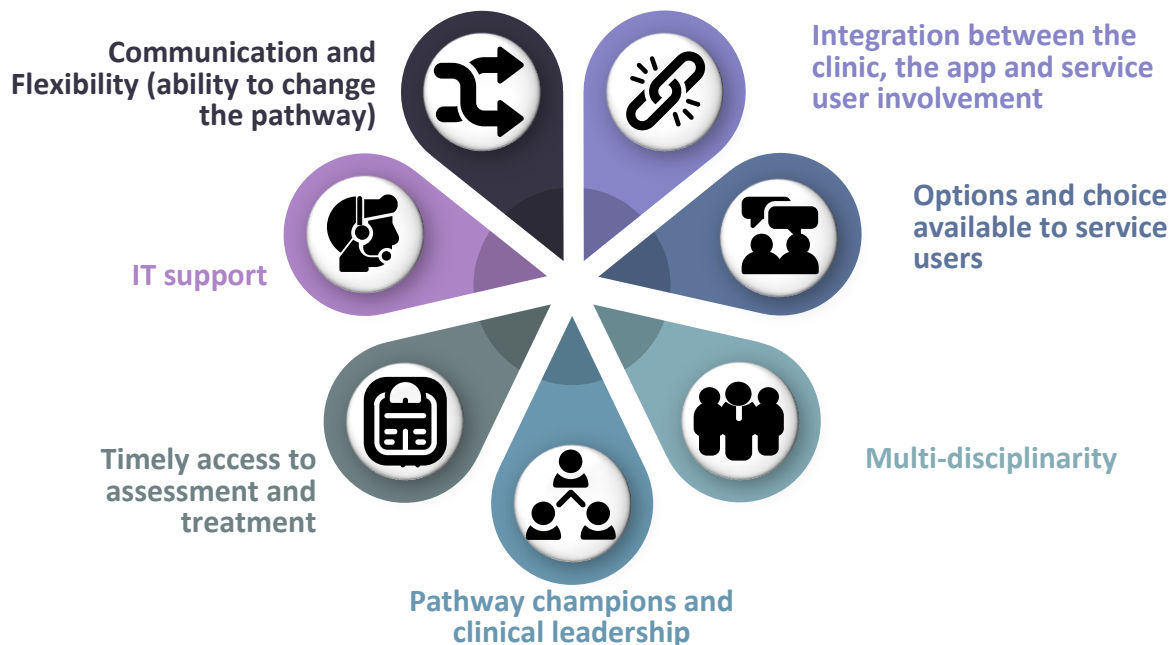
"You just need to look at the scores and you can see people are improving... I think that's actually boosting the confidence of the staff because they can all see that, and it makes them feel proud that they are helping people" (FG02T1)

- The intervention group exhibited lower depression symptoms when compared to the standard care group after six months of care ($p=0.47$) and significant improvement in symptoms over time ($p<0.001$).
- Recovery was observed in 35.4% of participants using the new service and clinically relevant improvement in 59.6% of participants in this intervention group.
- No difference in anxiety symptoms nor service user wellbeing were observed between the groups. Borderline differences in severity of suicidal ideation between groups was observed after six months of care, favouring the new service.

"I can safely say it is absolutely down to accessing the clinic because I've now got the tools and the access and the support that I think I need ..." (SU45)

"I would say a majority of the clients that I saw in the clinic that went on to have therapy, probably recovered at a quicker rate...or made some improvements" (KI06T1)

Key components or 'active ingredients' supporting service provision



Influencing contextual factors

- Changes to the local commissioning landscape emphasised the need for continued commissioner engagement, especially with regard to sustainability of the service.
- Primary care is experiencing increasing demand for services which impacts on the ability to deliver enhanced services.
- There is high demand regionally and nationally for mental health services. This issue of capacity limited the recruitment of mental health practitioners and influenced the presentation of service users who had greater severity of illness than expected.
- Brexit continues to create uncertainty in terms of staffing and sustaining services.

- The COVID-19 pandemic led to changes in the delivery of the service and impacted on the referral rates into the service.

Service resource use and cost

- In line with other enhanced services, the average total costs for the use of health and care services were higher – £591.66 (SD £519.19) for the intervention group compared with £230.88 (SD £378.83) for standard care ($p < 0.001$).
- Running the clinic was expensive largely due to the additional services provided, overheads and staff costs, especially on a Saturday. The number of service users seen was sub-optimal and, as a walk-in clinic, was unpredictable, which made balancing staff costs difficult. The use of the technology was seen as expensive.
- Costs were expected to reduce over time as a result of reduced appointment times (without the need to consent to take part in the evaluation) and the use of technology at scale. In the longer term, the benefits of people with mental health needs being seen early, by the right clinicians and with the right access to timely therapies, were expected to result in reduced treatment costs.

What could be improved, sustained or replicated

Findings were further organised to extract (1) what improvements were needed to optimise the pathway, (2) which key elements then required sustaining long-term and (3) which key elements should be replicated if a similar clinic was established elsewhere, despite the importance of different contexts.

	Improve (1)	Sustain (2)	Replicate (3)
1.	Widening referral and advertising to increase clinic use	Structured clinic based on triage and integration of services	Professionals in primary care with a special interest/skills in mental health
2.	Integration into standard practice, e.g. admin support	Providing options and choice in one place or dedicated clinic	Taking time with service users to provide holistic care
3.	Reduction of waiting times	Champions and effective leadership	IT support for professionals/services users for i-spero and implementation
4.	Peer support provision to complement services	Team reflection/communication with flexibility to adapt to need	Symptom tracking was seen as key to service user improvement
5.	Other methods of triage outside technology (i-spero) – accessibility	Timely access to treatment, avoiding waiting lists	
6.	Adapting delivery to reduce cost and improve sustainability	Retaining multi-disciplinary skill-mix	
7.	Further aligning delivery to needs of people with severe depression		
8.	Improving referral rates from other GP practices in the area		

2. Introduction

In the United Kingdom, one in six people aged 18 or over report symptoms of a common mental health disorder such as anxiety or depression¹⁻². The total cost of services for depression in England in 2007 was estimated to be £1.7 billion and projected to continue to rise in future³. Depression is a broad and heterogeneous diagnosis and may occur alongside other common mental health disorders such as anxiety⁴. Depression is typified by depressed mood and/or loss of pleasure in most activities and the severity is determined by both the number and severity of symptoms, as well as the degree of functional impairment⁴. Depression is treated with lifestyle interventions, psychological therapy and/or antidepressants; however, the success rate of treatments varies with most exhibiting modest success rates of around 50% for recovery^{1, 5}.

Depressive disorders are most often managed by a general practitioner (GP) in primary care, unless the severity of depression is such that care is required from a specialist⁶. Many service users seek help from their GP or local National Health Service (NHS) Improving Access to Psychological Therapies (IAPT) service but commonly have to wait some time for assessment and treatment¹. Moreover, the assessment and treatment provided by GP practices in accordance with National Institute for Health and Care Excellence (NICE) guidelines varies widely across the country and the quality of care critically depends on the individual GP's interpretation of guidelines and their own knowledge of mental health conditions⁴. Poor levels of detection, treatment and monitoring of depression have been highlighted in primary care settings⁷ leading to service users with depression exhibiting reduced health-related quality of life⁸. Despite the growing interest in the quality of care for depression, there has been little evaluation of this in primary care settings⁷⁻⁹.

Digital technology, including applications (apps) for mobile phones and tablets are being created to complement clinical care for common mental health conditions. More than 13 web applications and 35 smartphone apps are available in the NHS for depression, anxiety or stress¹⁰. There is also large diversity in how these apps work and what they provide to users; many act as, or feature, mood trackers which allow the user to plot their moods and general wellbeing on to a graph or scale¹⁰. Given the pace of change in these digital technologies, research to understand the quality and effectiveness of these apps is often missing, with no general requirement for technology providers to demonstrate beneficial outcomes through clinical trials or other means¹¹. However, in those with depressive conditions, smartphone apps have been shown to reduce symptoms with moderate positive effects¹². More research is required to understand how these technologies can support care provision which should be focused on understanding reach, adherence, barriers and cost¹¹. Furthermore, to have a public health impact, research on implementation in a 'real world' setting and application to prevention is required¹¹.

A 'walk-in' service was piloted for one year at GP services in Faversham, Kent to provide access to a multi-disciplinary team of health/social care professionals with specialist knowledge of mental health and wellbeing and a range of therapy options. Built into the service was the use of a novel digital technology, i-spero, designed to assist service users with managing their depression and to support healthcare professionals in clinical decision making and management. This evaluation of the new service aimed to identify changes in context regarding implementation and resource use, who and what was affected and how, the effects on user outcomes and experiences, plus the experience of healthcare professionals.

3. Methods

3.1. Overview of the intervention

With the support of NHS Canterbury and Coastal CCG (CCCCG) and funding from Innovate UK, a new care pathway was implemented as part of a local service re-design within a primary care setting across two GP services in Faversham, Kent. The aim was to provide a new integrated service pathway for those with low mood, anxiety and depression through a walk-in clinic setting utilising multi-disciplinary staff. The service comprised GP triage followed by multi-specialty care provision for treatment including access to anti-depressant therapy through GP prescribing, psychological therapy and wellbeing support at a single point of access. Assessment for psychological and talking therapies was provided within the clinic in partnership with a local Improving Access to Psychological Therapies ([IAPT](#)) provider to offer NICE recommended therapies, such as cognitive behavioural therapy (CBT), for common problems involving stress, anxiety and depression through healthcare professional or self-referral. Support for lifestyle and behaviour changes was provided by health trainers from the local [OneYou](#) services; a Public Health England supported initiative delivered by the NHS to provide services aimed at supporting people to stay fit, healthy and well. All service users were requested to use the i-spero digital technology (P1vital Ltd) in order to complete symptom assessments for triage and management of care. Appendix 1 provides a flow diagram illustrating the initial pathway designs implemented on 9th July 2019. As part of the service evaluation design (section 3.2), changes to the intervention pathway were allowed in order to maximise implementation during the pilot period. Changes made during the pilot year of the service are summarised in Appendix 2.

The [i-spero digital technology](#) is a web application that can be accessed online using a phone, tablet or computer. It is designed to be used by both service users and health/social care professionals to assist with triage, symptom assessment, treatment response, follow up and care planning for service user self-management. Service users were asked to use i-spero to assess and monitor their symptoms of low mood, depression and anxiety using validated assessments: Patient Health Questionnaire 9 (PHQ-9)¹³, Generalised Anxiety Disorder Assessment 7 (GAD-7)¹⁴ and the PReDicT test (Predicting Response to Depression Treatment)^{15,16} for assessing antidepressant treatment response. The i-spero technology also uses the results of these assessments and care planning management to inform health/social care professionals' care provision, remote follow up and to identify service users 'at risk' through alerts for symptom deterioration and suicidality.

3.2. Service evaluation design

This service evaluation was delivered by the Centre for Health Services Studies at the University of Kent and was conducted independently of the delivery and implementation of the intervention. The evaluation took place between July 2019 and August 2020 with participants recruited over a seven month period (July 2019 to January 2020) followed by six months of follow up from February 2020. The evaluation followed a mixed methods, observational feasibility study design, using an evidence integration triangle implementation research approach to identify changes in context regarding implementation and resource use, who and what was affected and how, the effects on user outcomes and experiences, plus the experience of healthcare professionals¹⁷. The information gathered was used to understand the 'active ingredients' for transfer and scalability and aspects that are making

a difference¹⁷. The evaluation was designed in line with the NICE evidence standards framework for digital health technologies¹⁸.

Specifically, the evaluation set out to answer the following questions:

- What impact has the systematic pathway had on service user experience and outcomes?
- What are the components of the care delivery model ('active/successful ingredients') that are really making a difference?
- What are the influencing contextual factors and how have they affected implementation and outcomes?
- What changes to the use of resources and activity have occurred and how have they impacted costs?
- What could be improved, replicated and sustained?

The evaluation was conducted alongside the roll out of the new service for low mood, anxiety and depression hosted at a single primary care GP practice in Faversham, Kent but offered referral and access to patients across two practices in the area and within a single primary care network (PCN). Participants involved in the evaluation were initially recruited across both practices, however, participants from the non-hosting practice had to be excluded from the evaluation analysis due to the inability to access data for use in the evaluation from participant medical records at this practice. Appendix 3 presents a flow chart of the evaluation and illustrates the sample groups and data collected. Data were collected from two sample groups as described below.

3.2.1. Intervention Group

An intervention group comprising prospective service users who had received six months of care for low mood, depression and/or anxiety from the new service (target sample n=100) who were over 18 years of age and had agreed to use i-spero to support their care. Those considered to require emergency assessment by a GP with a view to referral to secondary care were excluded unless they were subsequently deemed eligible for GP-based care. All service users attending the new service and fitting the eligibility criteria above were invited to take part in the service evaluation between 6th July 2019 and 1st February 2020.

3.3.2. Standard Care Group

A standard care group comprising service users identified in the GP practice records as having low mood, depression and/or anxiety (service users who had a code for low mood, depression and/or anxiety and/or who had been prescribed an antidepressant) prior to the introduction of the new service and who had not attended the new service (target sample n=100), were over 18 years of age and able to provide consent online. All eligible service users between 1st July 2018 and 30th June 2019 were identified from the GP practice records and were sent an email containing an information sheet and details of how to take part in an online survey on one occasion only. A second email and a single text message were sent to non-responders of the initial email.

3.3. Ethical considerations

The project was sponsored by the University of Kent (Reference: ResGov 414) and given a favourable opinion by the School for Social Policy, Sociology and Social Research SRC ethics committee (Reference: SRCEA id 232). All service users were provided with full written information and provided with opportunities to ask questions. If

willing to take part, written consent was then received by the consulting health/social care professional for the intervention group and online consent was provided for the standard care group. If service users using the new service did not want to take part at the first visit, they were given the option to change their mind at any time and, if so, to contact the research team. Participants were free to withdraw from the evaluation at any time and this was made clear in the information sheet and consenting process, including the fact that data collected up to the point of withdrawal would be used according to the original consent unless they specified otherwise. Participants were also made aware that taking part would not affect the care they received in the service.

As this was an observational evaluation, the risks to service users was low. The evaluation and data collection was designed to create minimal burden on participants and where significant time was needed to provide data e.g. interviews, these elements were optional. Suicidal thoughts are common in service users with depression. Such thoughts obviously indicate a risk of suicide, although this risk is itself relatively small. i-spero measures suicidal thoughts within the PHQ-9 questionnaire and, if indicated, the healthcare team were notified automatically by i-spero. If a research team member was concerned about the health or wellbeing of a participant when in contact with them or from symptom data received from the control group, the participant's GP was contacted with the participant's consent and following the evaluation duty of care protocol.

3.4. Public involvement in the project

In partnership with Maidstone and MidKent Mind (project partner), a public involvement group was established to advise the evaluation throughout. Five members were recruited from Mind support groups who had lived experience of low mood, anxiety or depression, interested members of 'Opening Doors to Research' patient and public involvement group (Centre for Health Services Studies, University of Kent), or from local GP practice patient participation groups. The public involvement group was involved in assessing and recommending improvements to the i-spero prototype, design of the evaluation, participant information sheets and documents, reviewing clinic advertising and results during the evaluation, and reports and public dissemination activities. Appendix 4 provides a summary of input and changes made as a result.

3.5. Data collection

A mixed methods approach was used to collect data for analysis.

3.5.1. Quantitative data

Outcome, experience and economic data for the intervention group were collected using the i-spero web application at baseline, 4-8 weeks and six months of received care. Standard care group data were collected using a single timepoint online survey for participants who had received at least six months of care. All other data was collected from participants' medical records with consent for both groups (included demographics, past medical history, medication and primary care service use). Participant-reported symptom and wellbeing outcomes were measured using validated questionnaires (PHQ-9¹³, GAD7¹⁴, ICECAP-A¹⁹, EQ-5D-5L²⁰ and LTC-6²¹). At the six-month

time point, intervention group participants also completed a service experience questionnaire designed for the study with closed questions.

To understand representativeness of the sample populations, anonymised data were also collected from the i-spero application and the GP practice which included demographic data (sex, age, co-morbidities and anti-depressant medications) for all services users coded with an appointment for depression during the evaluation recruitment period plus mean, minimum and maximum PHQ-9 and GAD7 score for all services users using the new service during the evaluation recruitment period.

3.5.2. Qualitative data

Qualitative data were collected from intervention group participants only. At consent, participants were invited to share contact details to take part in two optional semi-structured telephone interviews (n=15-25) at 4-8 weeks and around the six-month follow-up time points to explore their experiences of receiving the service, the technology involved and to identify the facilitators and barriers to sustaining the service. Aspects relating to changes in their health, and service use behaviour were also explored. In addition, qualitative focus groups (n=6-8 people each) and interviews were undertaken with the new service implementation staff at 6-8 weeks after the start of the new service and again at 9-12 months. These data explored the experience and nature of the new service provision to identify any challenges, 'active ingredients' and changes during development and roll out of the new service, successes, transferability and sustainability. Findings from early focus groups (6-8 weeks post intervention start date) were fed back to the project steering committee and the health/social care provider team to enable rapid feedback into practice of what was working and what was not, so changes could be made and observed in real time. Telephone interviews were also conducted with 5-10 wider key informants (e.g. other GP practice staff involved, other health/social care professionals, technology/other providers and healthcare commissioners in the Kent region) at month 11-12 in order to gain a wider perspective of the potential impact of the intervention. Field notes were written up by researchers during qualitative fieldwork to capture the context and environment at the site as the intervention was being rolling out. Notes included detailed summaries of activities, events and behaviours and the researcher's initial reflections on them²².

3.6. Sample size and data analysis

3.6.1. Sample size

The evaluation aimed to achieve 100 service users taking part in each sample group. All participants in the intervention group were followed up for six months. An attrition rate of 20% at six months was estimated, leaving the sample for analysis as a minimum of 80 participants. The aim of data analysis was to analyse both quantitative and qualitative data individually according to the specifications outlined below, and then to blend the data through data triangulation to address the research questions (see 3.2).

For the standard care group, all service users presenting to the GP practice hosting the new service, who met the inclusion/exclusion criteria, were invited to take part in the evaluation. Data from a single practice in Faversham with a population of 18,000 patients, suggested an estimate of 17 service users attending each week for low mood, depression and/or anxiety. As the evaluation was intended to be conducted across two practices of similar size,

approximately 800 service users were anticipated to have received an episode of care for low mood, depression and/or anxiety (and/or prescribed an antidepressant as per the control group definition) at least six months prior to the implementation of the new service. With an estimated 10% uptake, the target sample size for the standard care group was a minimum of 80 service users.

In this study context, the usefulness of an *a priori* power calculation would be limited. Given the feasibility nature of the study, we did not have the necessary parameters to assess the effect size of the expected difference between experimental conditions. However, it was possible and more meaningful to perform a sensitivity power analysis. This revealed that with the expected and adjusted sample size of $n=80$ in each condition, a one-tailed hypothesis with $\alpha=0.05$ for a between subjects t-test, we would have enough power at $\beta=0.80$ to detect a medium to small effect size of $d=0.39^{23}$.

3.6.2. Quantitative data analysis

Participants were excluded from the quantitative analysis of outcomes and economic analysis in the intervention group if they were registered at the GP practice in Faversham but not participating in the evaluation (intervention group, $n=18$), did not consent to use of their medical records ($n=3$), did not have any i-spero data ($n=3$), deregistered from Newton Place Surgery before the end of the study ($n=2$) or did not complete follow-up visits within window (intervention group, $n=3$). Exclusions from the standard care group were for participants who did not provide full online consent ($n=6$, all not consenting to use of their medical records), they had used the new service ($n=2$) or incomplete data were obtained in the survey ($n=6$).

Quantitative data were analysed using SPSS (v11) and Stata SE (v15.1) software. Descriptive statistics were used to analyse all quantitative data and compared where available between standard care and intervention groups using appropriate statistical tests, which included parametric as well as their non-parametric equivalents (Wilcoxon Mann-Whitney test, independent sample t-test or Chi-squared test). The aim was to establish any significant differences between the groups at the six-month time point and within the intervention group only to look at changes over time at the 4-8 week and six-month time points.

3.6.3. Qualitative data analysis

Interview, focus group and field note data were transcribed and analysed using the content analysis software NVivo (v10). Data were subject to content analysis using Flick's (1998) approach²⁴. In short, a predetermined coding framework was used to categorise data designed in line with data collection question guides. Transcribed data and quotes were sorted into the predetermined categories and coded according to the origin of the quotes. Each category was then analysed into themes using the quotes to justify interpretation. Data that did not easily fit into the predetermined categories was set aside and separately thematically analysed. To ensure a credible and unbiased analysis, a second researcher checked the analysis trail.

3.7. Health economics analysis

The health economics analysis aimed to assess changes to resource use and activity that occurred as a result of the new service and how these have impacted costs. Costs were calculated from the perspective of the health and

social care provider (NHS). Additional costs incurred by the service user, including out-of-pocket expenses and loss of earnings were limited and considered in an additional analysis to capture the societal perspective. The aim of the main analysis was not to perform a full economic evaluation whereby the cost-effectiveness of the new service would be assessed compared with standard care. Nevertheless, and cautious of the small sample size for the control group, we attempted to estimate an incremental cost-effectiveness ratio (ICER), which could inform a larger study with an economic evaluation element in the future. In order to calculate the ICER, we further had to consider a measure of effectiveness, expressed as quality adjusted life years (QALYs) in line with the NICE reference case²⁸.

In addition to the above exclusions for outcome data, some participants in the intervention group did not have baseline health-related Quality of Life data (QoL, n=9). It is not common practice to impute missing QoL data at baseline, hence these were excluded from the health economics analysis sample. Further, some participants did not complete their follow-up assessment at 4-8 weeks (10%) and six months (38%) despite the text reminders sent. For these cases, missing QoL and health and social care costs were imputed using multiple imputations via chained equations²⁵⁻²⁶. We assumed missingness at random at each time point in order to use as much as possible of the available information for each variable. As a rule of thumb the number of imputations should equal or exceed the fraction of missing information²⁷, therefore, we ran a multiple imputation analysis with 40 imputations generated. To ensure best fit of the imputed results, imputations were based on the following predictor variables: sex, age, number of comorbidities, family depression history, prior prescription of anti-depressants, QoL score at baseline and PHQ-9 total score at baseline. The base case sample (i.e. after imputation in the intervention group) was 111 service users (40 in the control group and 71 in the intervention group); this is the sample used in the health economics analysis.

3.7.1. Resource use data

Resource use data specific to running the Saturday clinics provided by the GP practice were considered separately as part of costing the new service (see Appendix 5.1). To ensure accurate and pragmatic costing of the Saturday clinic for the intervention group, a micro-costing approach was used whereby an intervention cost was calculated for each participant, accounting for the number of times they attended a Saturday clinic as well as the type and duration of appointments they had during these visits. Additional costs considered in these calculations were the time of reception and management staff (including admin and overtime), which was proportionate to the total number of service users attending the clinic each week. Finally, any i-spero hosting and helpdesk costs incurred by the app developers (£465 per month between July 2019 and June 2020; £230 per month between July 2019 and February 2020) were split across the participants in the intervention group, accounting for the total number of users attending the clinic per week.

The remaining resource use data were collected at six months from the participants (via i-spero in the intervention group; online survey in the standard care group) and GP practice records. We broadly divided resource use into the following categories: primary care services, health trainer wellbeing service ([OneYou](#)), Improving Access to Psychological Therapies ([IAPT](#)) service, community-based services and hospital inpatient and outpatient services. Resource usage was converted into costs using unit cost figures from the Personal Social Services Research Unit (PSSRU)²⁹, the Department of Health and Social Care National Schedule of NHS costs³⁰, and information from local IAPT and OneYou services (see Appendix 5.2).

Unit costs for any prescribed anti-depressant medication were obtained from the electronic market information tool³¹. Medication details including the dosage, date started and date stopped were entered into the practice electronic system and extracted by the practice research staff on behalf of the evaluation team for a period of six months. The number of days on which the medication was taken was calculated using the aforementioned dates. All the unit costs and dosage details for the anti-depressant medication prescribed to the study groups are shown in Appendix 5.3. These unit costs together with the package and dosage details as well as the number of days the medication was taken were combined to calculate the cost of anti-depressant medication for each service user. Differences in costs across time points and between groups were evaluated using Mann-Whitney *U*-tests. The currency used was the pound sterling (£) and 2020 was the reference financial year.

3.7.2. QALYs

QALYs represent a quality-of-life-weighted survival value in which 1 QALY is equivalent to 1 year of full health. Participants' health-related quality of life (QoL) was assessed using the EQ-5D-5L instrument³²⁻³⁴ at baseline, 4-8 weeks and six months for the intervention group, and at six months for the standard care group. Since there was no indication of the QoL for the standard care group (required for the calculation of QALYs) at baseline, we strictly assumed that they had the same QoL as similar respondents in the intervention group (i.e. we matched respondents based on age and sex at baseline). In line with recent NICE guidance, and in the absence of an acceptable valuation set for the EQ-5D-5L, individual responses to the instrument were converted into health-related QoL scores using a validated mapping function tool³⁵⁻³⁶. Changes in QoL scores across time points and between groups were evaluated using two-sample *t*-tests. Health-related QoL scores were multiplied by the proportion of 1 year the time period represented (for example, baseline to six months=0.5) to calculate QALYs. Average QALYs between adjacent time points were calculated to generate smooth estimates between time points using the area under curve approach as shown below:

$$\begin{aligned} \text{QALY_control} &= \{(\text{QoL_baseline} + \text{QoL_6months}) / 2\} \times 0.5 \\ \text{QALY_intervention} &= \{[(\text{QoL_baseline} + \text{QoL_midpoint}) / 2] \times a\} \\ &\quad + \{[(\text{QoL_midpoint} + \text{QoL_6months}) / 2] \times b\} \end{aligned}$$

where 'midpoint' refers to the first follow-up assessment; a and b are the proportions of one year the first follow-up represented which vary by participant in the intervention group as they completed the assessment between four and eight weeks from baseline.

4. Results

Newton Place Surgery is a medium size practice with a list size of 15,348 patients (2019-2020 data³⁷). It is one of two practices in Faversham which make up a Primary Care Network (PCN). Quality and Outcomes Framework (QOF) data³⁷ indicate an incidence of depression in 2019-2020 of 16.5% of the practice list (n=2537) which is slightly higher than the national average of 11.6%. The total urban population of Faversham is 20,110, of whom 48.1% are male and 97.7% are white (2019 mid-year population estimates, Kent County Council³⁸). Just under one-fifth (18.4%) of the population are aged 64 years or older, with 18.9% of the population living with a long-term health condition that limits day to day activity and 5.5% reporting to be in bad or very bad health³⁸.

4.1. Intervention use

4.1.1. Walk-in clinic use

The start of the new service began on 9th July 2019. In the first year of operation (9th July 2019 until 25th July 2020), a total of 605 people (232 new service users, 374 follow up appointments) used the new service (Figure 1). The average number of service users attending was 11 per week (mean = 10.8, min-max 3- 26 in any one week), comprising an average of four new appointments (mean = 4.1, min-max 0-12 in any one week) and seven follow up appointments (mean = 6.7, min-max 0-26 in any one week).

Figure 1: New service footfall during the first year of operation.

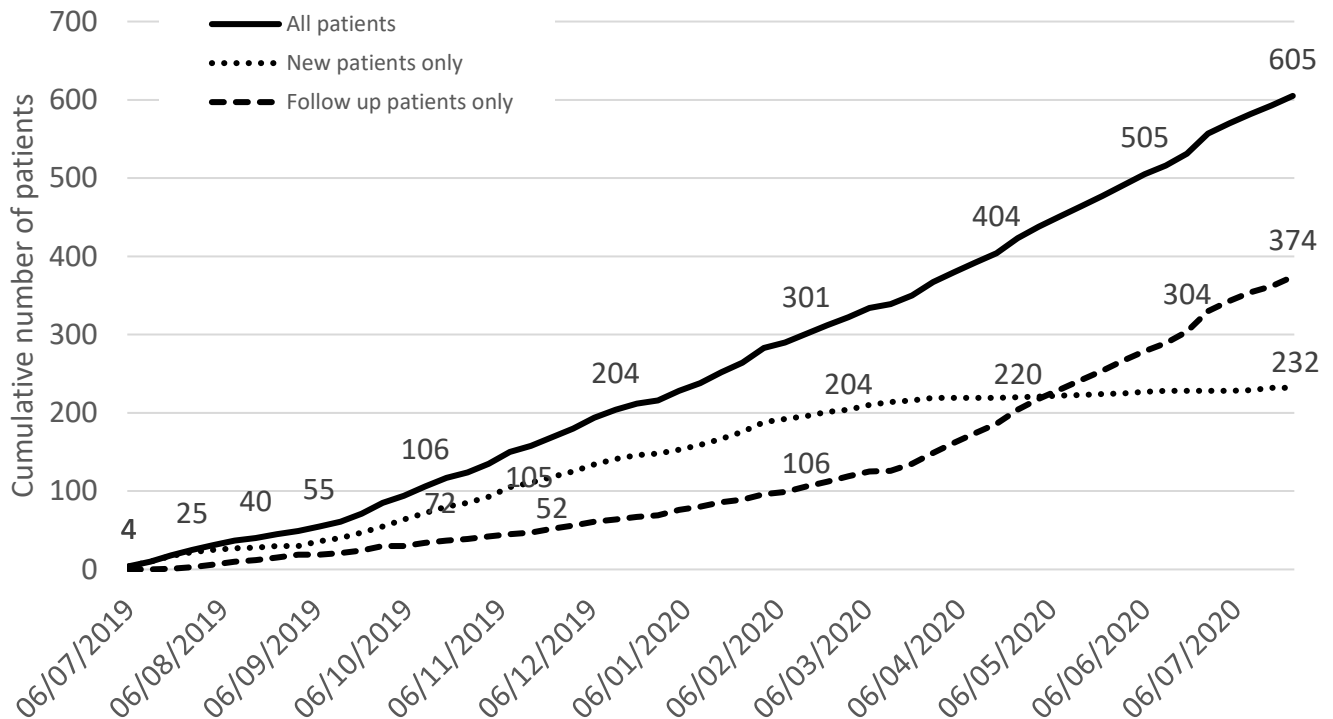


Figure 1 shows the weekly number of people attending the new walk-in clinic service for low mood, anxiety and depression. The y-axis indicates cumulative number of service users each week (solid line), number of weekly new services users attending (dotted line) and number of follow up appointments (dashed line) with key data points indicated on the graph. Clinics occurred weekly, however; x-axis dates indicate the first clinic of each month during the year of operation.

4.1.2. Use of other services within the intervention – IAPT and OneYou services

During the study recruitment period (July 2019-February 2020), 102 service users were seen by IAPT on a Saturday morning as part of the pilot. Of these, 70 (88%) were taken on for a course of treatment, with five appointments per service user on average. A total of 170 appointments were delivered on weekdays, with the most common treatment being Step 3 Counselling^a, and the least common Step 2 Counselling^a. In the same period, 86 service users were seen by OneYou on a Saturday morning, and of these, 29 (34%) accepted the full service. Fewer appointments (n=67) were delivered outside of the walk-in clinic on a Monday or a Friday where appointments were arranged after clinic attendance. The most common goal themes set by the service users included for example, reducing stress/anxiety, increasing exercise and reducing alcohol/drug consumption (for more details, see Table 1).

Table 1: OneYou common goal themes set by the service users

<u>Wellbeing</u>	<u>Healthy eating</u>	<u>Alcohol and/or drug use</u>
✓ signposting to community assets	✓ increase fruit and vegetables	✓ reduce alcohol consumption
✓ reduce stress/anxiety	✓ complete a food diary	✓ reduce drug use
✓ connect with others	✓ eat regular meals	
✓ take up a hobby	✓ plan meals and write shopping list	
✓ medication and breathing exercises	✓ increase light exercise	
✓ learn something new	✓ increase moderate exercise	
✓ volunteering	✓ contact exercise support programme	

Source: North and West Kent OneYou

4.2. Evaluation sample groups

4.2.1. Sample group recruitment

All those attending the new service were invited to take part in the evaluation as part of an intervention sample group. Recruitment occurred between the start of the new service on 6th July 2019 and 1st February 2020 with a total of 109 participants recruited within this period (exceeding the recruitment target of n=100). An average of 3.5 service users (min-max 0-9) were recruited each week, with 38.5% of those invited going on to consent to the evaluation. Figure 2 below summarises recruitment to the intervention group over time. No participants withdrew consent for the evaluation during the study. The final intervention group sample was n=80 after exclusion of participants (see Methods for exclusions). The percentage of participants who did not complete follow up data was 17.5% (n=14) at the 4-8 week visit and 41.3% (n=33) at the six-month follow up visit assessed by completion of both PHQ-9 and GAD7 symptom questions at these timepoints.

a NHS Stepped Care Model for depression services includes: Step 1 for recognition of symptoms is assessment, Step 2 for mild depression is watchful waiting with guided self-help, computerised cognitive behavioural therapy, brief psychological interventions and wellbeing support, Step 3 for moderate or severe depression is medication, psychological interventional and social support, Step 4 and 5 is for recurrent or treatment resistant depression and risk to life or severe self-neglect and treated with combined treatments and more complex psychological or other interventions.

<https://www.bacp.co.uk/media/1977/bacp-choice-of-therapies-in-iapt.pdf>

Qualitative data were collected through individual interviews with participants receiving the intervention and a mixture of focus groups and individual interviews with health professionals and wider key informant stakeholders. Of the 72 participants who consented to being contacted about taking part in qualitative interviews, 35 took part in an interview 6-8 weeks after their first visit to the clinic, exceeding the 15-25 interview target. Of these 35, 20 also took part in a short follow-up interview six months after the initial visit to the clinic. All interviews were carried out over the phone.

Two in-person staff focus groups were held 6-8 weeks after the start of the clinic. Seven staff took part in the operational staff focus group, and three were present at the managerial staff focus group. These were followed by five individual telephone interviews with focus group participants (one representative from each distinct profession/role took part). Due to the restrictions imposed by the COVID-19 pandemic, staff focus groups could not be held 9-12 months after the commencement of the clinic. Instead, seven individual telephone interviews were held, three with managerial and four with operational clinic staff. Recruitment exceeded the original target for this group.

A further six telephone interviews were held with eight wider stakeholders; four of these were individual interviews, while the remaining interviews had two participants in each. Wider informants included staff at the GP surgery referring to the clinic, but not involved in clinic delivery, technology providers and IAPT, as well as One You service managers whose staff were part of the clinic. Recruitment met the original target for this group.

Figure 2: Recruitment to the intervention group.

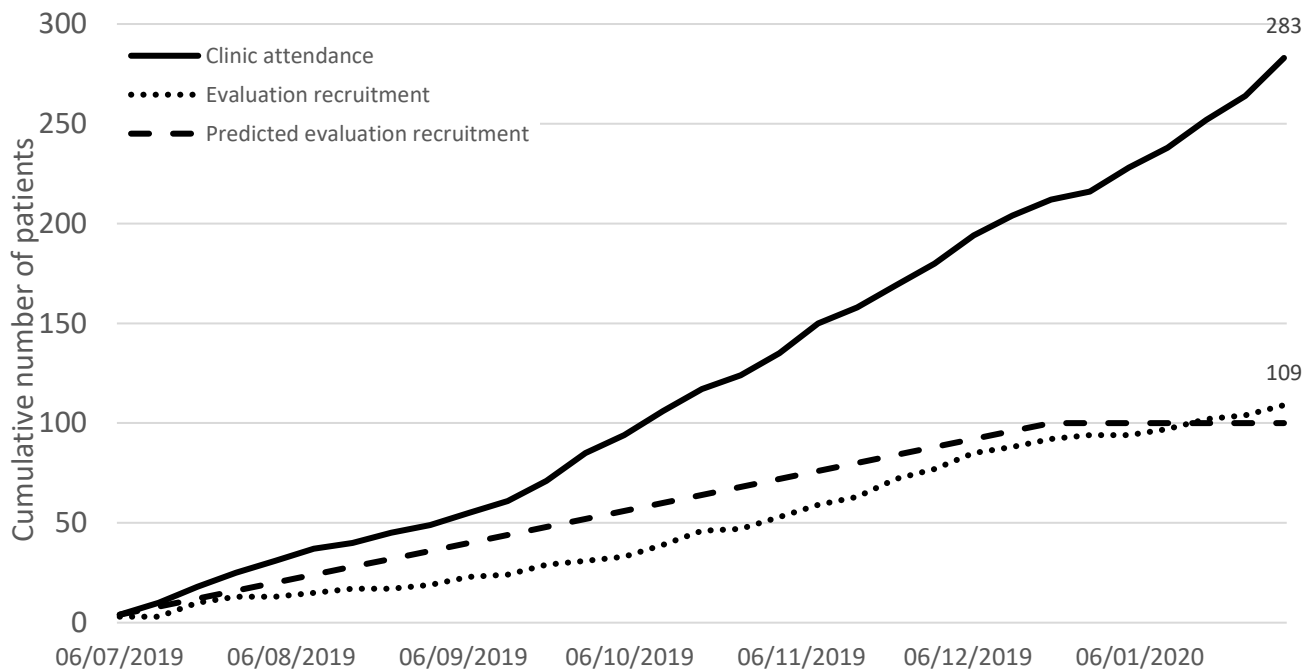


Figure 2 - cumulative recruitment of service users (y-axis) over time to the intervention group (dotted line). This is compared to cumulative clinic attendance (solid line) which includes new and follow up service users. Predicted recruitment prior to study start is shown with a dashed line. Weekly clinic data is represented, however, only the first weekly clinics of the month are shown on the x-axis.

For a standard practice comparison sample, practice records were used to identify service users who had not used the new service but had received at least six months of standard care for low mood, depression and/or anxiety between 1st July 2018 and 30th June 2019. A total of 414 eligible service users were identified and invited to take part between 23rd September 2019 and 30th April 2020, of whom 48 consented to take part in the evaluation via online questionnaire (12.0% response rate, exceeding estimated response rate of 10%). Accounting for those who had used the new service and those who did not complete the full questionnaire or provide full consent, 40 service users provided complete data for use in the standard care group. Fifteen of the 48 consenting participants (31.3%) in this group provided data that warranted reporting to their GP to ensure patient safety. This was due to indications from symptom questionnaires that they continued to have severe symptoms of depression and/or concern of self-harm. This was carried out with the consent of the participant. No participants withdrew consent for the evaluation during the study.

4.2.2. Sample group characteristics

Table 2 below shows a comparison of the characteristics of the evaluation sample groups. Both groups illustrated similar age, previous history of medicated depression and co-morbidity characteristics. The standard care group consisted of proportionately more females than the intervention group. Data on family history of depression were confounded by a lack of data for standard care participants.

Table 2: Sample group characteristics

	Intervention group (sample n=80 unless specified)	Standard Care group (sample n=40 unless specified)
Age, median, min-max	37, 18-69	42, 18-69
Sex, % male (n)	45.0% (36)	17.5% (7)
Previous history of medicated depression, % (n)	72.2% (57) ^a	77.5% (31)
Family history of depression, % (n)	Yes: 73.7% (42) ^b	Yes: 62.5% (5 ^c)
Number of co-morbidities, median, min-max	1, 0-6	1, 0-9

^a In one participant previous medication for depression was not recorded in their medical records, leaving a sample of n=79 for this variable

^b For twenty-three participants, family history of depression was not recorded in their medical records giving a sample of n=57 for this variable

^c Only 5 participants had this data recorded in their medical records in the standard care group

Table 3 compares the evaluation sample group populations with both the total intervention population attending the new service in a similar period and all service users attending the practice for depression, low mood or anxiety including those on medication both at the walk-in clinic and those attending standard practice appointments during normal practice weekly hours. Apart from higher proportions of females in the standard care evaluation group as described above, evaluation samples were representative of service users both attending the intervention clinic and those generally presenting to primary care.

Table 3: Comparison of sample group characteristics to other GP practice populations

	Total (n)	% male	Baseline PHQ-9 (mean score, min-max)	Baseline GAD7 (mean score, min-max)	Number of co-morbidities (median, min-max)
Intervention group	83	47.0	17.3, 3-26	14.2, 1-21	1, 0-9
Standard care group	40	17.8	N/A- data unavailable ³	N/A- data unavailable ³	1, 0-6
Total intervention population ^a	122	42.6	16.4, 2-26	14.0, 1-21	N/A- data unavailable ^d
All services users ^b	547	38.2	N/A- data unavailable ^c	N/A- data unavailable ^c	N/A- data unavailable ^d

Min., minimum; Max., maximum.

^aTotal number of patients attending Saturday clinic during the recruitment period 6/7/2019 and 1/2/2020

^bAll patients presenting to GP practice between 1/7/2019 and 31/12/2019 for low mood, anxiety or depression including those on anti-depressants whether they attended standard appointments and/or the Saturday clinic

^cData not routinely collected as part of standard care practice

^dData not feasible to extract from practice medical records.

For the intervention group, over two-thirds (85.0%, n=68) presented as a clinical case using IAPT service definitions (PHQ-9 score of ≥ 10 and GAD7 score of ≥ 8)³⁹. Many attending the new service presented with severe depression and/or moderate anxiety (Figure 3). The mean PHQ-9 and GAD7 scores for the new service (intervention group only) at baseline were 16.99 (SD 6.019, min-max 3-26) and 14.01 (SD 5.179 min. 1, max. 21), respectively. Although there are no data to make presentation severity comparisons with the standard care group due to lack of comparative assessment in practice, Table 2 shows that both groups exhibited similar previous history of medicated depression. Just under half of the intervention group (48.8%, n=39) had no suicidal ideation as assessed by question 9 of the PHQ-9, with 25.0% (n=20) indicating suicidal thoughts on more than half of the days or nearly every day in the last two weeks.

Figure 3: Severity of depression and anxiety assessments at baseline for the intervention group (PHQ-9 and GAD-7 scores)

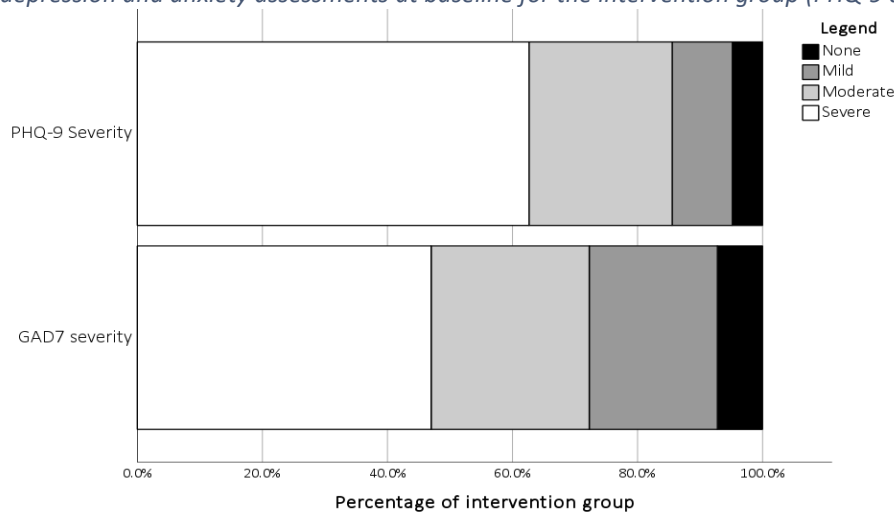


Figure 3 shows the severity of participant depression and anxiety as measured by PHQ-9 score and GAD7 score, respectively. Severity is assigned by scores for the PHQ-9 (depression) and GAD-7 (anxiety) symptom questionnaires and depicted from left to right above where: >15 is severe (orange), 11-15 is moderate (crimson), 5-10 is mild (green), 0-4 is none (blue).

4.3. What impact has the systematic pathway had on service user experience and outcomes?

4.3.1 Service user experience of the care pathway

Participants rated the new walk-in clinic intervention highly. Comparison of participants between intervention and standard care groups indicated significantly higher satisfaction for those receiving the intervention (Table 4). Data from the intervention group service user experience questionnaire conducted at the six month visit indicated that 95.5% (n=43) of participants were happy with the care they received (answered strongly agree or agree to the statement: ‘I am happy with the care I received at the walk-in clinic’). Qualitative data supported these findings indicating high satisfaction with the service as detailed in Table 5.

Table 4: Comparison of service user experiences between sample groups – data collected at Visit 2 (6 months)

Service user experience	Intervention group (n=46) n (%)	Standard care group (n=39) n (%)	p-value (Pearson’s Chi-squared test)
Fell short of expectations	6 (13.0)	20 (51.3)	<0.001
Just met expectations	14 (30.4)	11 (28.2)	
Exceeded expectations	26 (56.5)	8 (20.5)	

Table 5: Qualitative interview findings on service user experience

Theme	Illustrative quotes and other supporting information
<i>Meeting expectations:</i>	
The majority of service users were highly satisfied with the service; felt that service met or exceeded their expectations	<p>“[I]t absolutely exceeded my expectations because I wasn’t planning on walking away with a really quite awesome care plan and the service I received having seen two different professionals from different sides of depression treatment within twenty minutes of each other and walking out feeling very positive that it was going to have a very beneficial effect for me” (SU04^b)</p> <p>“[I]t definitely exceeded my expectations because it was like a wrap around care...” (SU41)</p>
Clinic surpassed their expectations compared to what they normally experience during general GP appointments or care previously received for depression	<p>“100%. Yeah, I think it’s much much better than any other service I’ve had around mental health.” (SU59)</p> <p>“To be quite honest I had no expectations in fact I thought I’d be disappointed because I though it’s a brilliant idea but it’s not going to work. The NHS as I said before has let me down, let my son down [who died by suicide]. So I actually had no expectations and so it had to exceed it. [Laughter] No matter what...and by far</p>

^b Quote attributions starting with ‘SU’ (e.g. SU04) denotes service user interviews, ‘KI’ stands for key informants, including operational and managerial clinic staff, and ‘WS’ stands for wider stakeholders. Interviews with key informants and wider stakeholders are also marked with T1 (referring to the first wave of data collection soon after the clinic started) and T2 (denoting interviews 10 months after the start of the clinic). FG1 refers to focus group with operational staff and FG2 refers to a focus group with managerial staff at the clinic. Joint interviews with multiple wider stakeholders have two participant numbers separated with a dash.

	<i>it has. It's given me faith again that people do know what they're talking about" (SU36)</i>
Reasons for symptom improvement:	
Services users and clinic staff usually related improvement near-exclusively to the help they received at the clinic and receiving support from multidisciplinary team	<p><i>"I can safely say it is absolutely down to accessing the clinic because since then my grandmother's passed away and I haven't had an episode again, nothing like what happened because I've now got the tools and the access and the support that I think I need, mechanisms in the way that I deal with bereavement and all of that that it hasn't manifested itself in a manic panic sort of episode" (SU45)</i></p> <p><i>"I would say a majority of the clients that I saw in the clinic that went on to have therapy, probably recovered at a quicker rate...or made some improvements" (KIO6T2)</i></p>
Service users welcomed having access to multiple types of care within a single clinic	When asked if participants were happy to have access to other care services like One You and IAPT in one place, 76.8% (n=33) strongly agreed or agreed.
Concerns around anonymity:	
<p>While concerns were relatively infrequent, an area of particular concern was around the walk-in nature of the clinic.</p> <p>A small number indicated that this may be due to feeling exposed and potential loss of anonymity.</p>	<p>67.4% (n= 28) of participants strongly agreed or agreed that they were concerned about attending a walk-in service.</p> <p><i>"I felt really sorry for this bloke I sort of know, who was plonked in the corner looking really glum and he's sort of someone I only know to say hello to, I don't know him well but obviously he's there because he's feeling down and so am I, so it was really awkward and I'd sat down almost right next to him without looking that it was him, noticing who he was, so I suppose he felt really uncomfortable which made me feel uncomfortable, so yeah, it would have been better maybe in a mixed waiting room" (SU66)</i></p> <p><i>"So everyone's coming in for their depression low-mood clinic, everyone's sitting there, it's not very confidential then is it? You know, if I'm sitting there and if I was living in Faversham and I was kind of sitting there and I can see my neighbour sitting there as well, you all know why you're there" (WS08)</i></p> <p><i>"[S]he [service user] said the first Saturday she came in she saw who was at reception, she knows them...she came into the building and then she left because actually she didn't want people to know ..." (FG02T1)</i></p>
In contradiction, some service users said that placing the clinic at the GP surgery helped to address stigma around mental illness which may hold some people back from seeking support, and helped service users to maintain confidentiality around their difficulties	<p><i>"[I]t's quite comforting when you're in the reception area and you see there's lots of people coming and going and they all look perfectly normal and you think, well there's lots of normal people out there like me who are going through similar sorts of thing and not that I ever talk to someone, but just to look at someone or smile at someone or whatever, it's just, it's just like it almost gives you a sense of not feeling quite so isolated of weird or exposed" (SU54)</i></p> <p><i>"I think the biggest problem in life we suffer is the stigma against mental health and I think the one of the benefits of it being a doctor surgery is the fact that if you are embarrassed or you have got the stigma it's a shameful thing no one knows you're going for mental health" (SU29)</i></p>

4.3.2. Service user experience of i-spero

On average, participants logged in to use i-spero 22 times or approximately once a week (min-max 2-150 equating to nearly once a day). Just over half of participants used i-spero less than or once a week (56.4%, n=47), one third of participants (37.2%, n=31) used the technology two to three times a week and a small minority more frequently (6.0%, n=5 used i-spero more than three times a week).

The majority of participants were happy to use the i-spero technology to guide their care and management (Figure 4). Participants also found i-spero easy to use and 87% (n=40) indicated that they would use the technology again if it was offered to them. Participants did not experience problems with their internet connection (65.9%, n=29) nor found it difficult to access i-spero (65.1%, n=28) on their relevant hardware (computer/phone/tablet). One-third of intervention group participants (34.8%, n=16) did not feel worried that other people (referring to professionals) may access the information collected about them in the i-spero web application. Participant views of i-spero from qualitative interview data are described in Table 6. Suggestions for improvement or development of the i-spero technology provided by service users in interviews are summarised in Appendix 6.

Figure 4: Service user experience of using i-spero in their care pathway

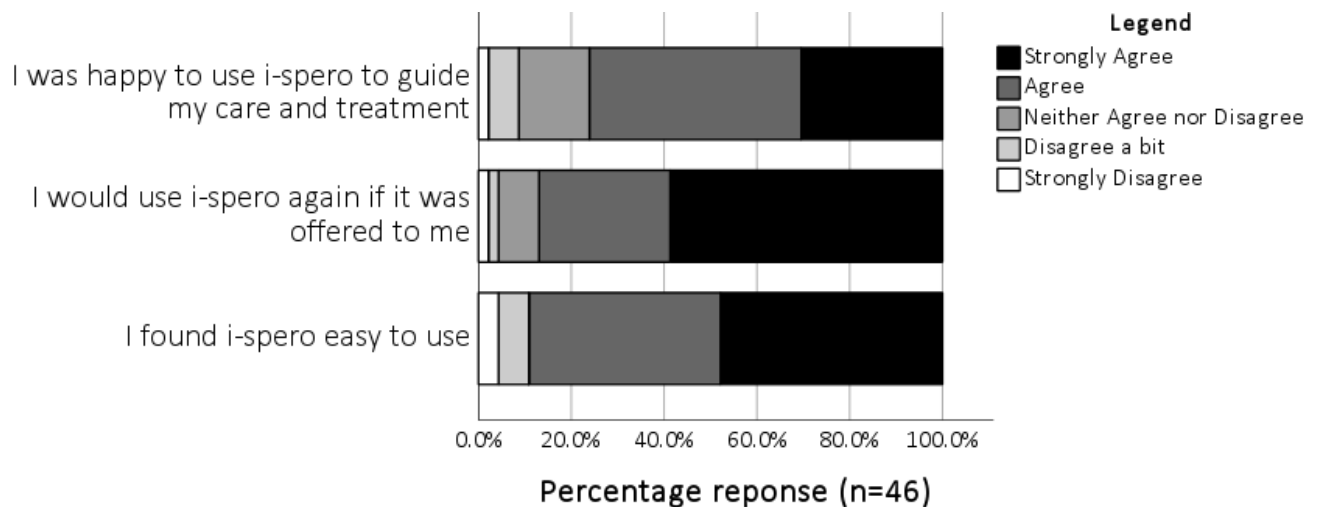


Figure 4 shows the responses to a service experience questionnaire completed by participants in the intervention group at the six-month visit (n=46). Data relating to the questions asked on the y-axis are displayed with respondents asked to answer whether they Strongly agree (blue), Agree (green), Neither Agree nor Disagree (red), Disagree a bit (yellow) and Strongly Disagree (black).

Table 6: Qualitative interview findings on i-spero use

Theme	Illustrative quotes and other supporting infomatoin
<i>Ease of i-spero use:</i>	
Service users found i-spero straightforward to use and clinic staff felt that i-spero enabled service users to visualise their progress	<p>"Yeah, I really like it. I think it is a fantastic tool and I think it does need to be nationalised" (SU29)</p> <p>"Although [service users] didn't feel necessarily that things were better...actually it illustrated the point of view from where they were a year ago, or six months ago, things were improving" (WS09)</p>

	<p><i>"You just need to look at the scores and you can see people are improving... I think that's actually boosting the confidence of the staff because they can all see that, and it makes them feel proud that they are helping people" (FG02T1)</i></p>
<p>The only aspect which attracted substantial negative remarks in terms of ease of use was the number and length of questionnaires within the i-spero technology</p>	<p>Despite over half of intervention group participants (56.5%, n=26) disagreeing when asked if there were too many questionnaires to do in i-spero after six months of care, the length of the PReDicT test¹⁵ within i-spero in particular was seen as a barrier:</p> <p><i>"[T]hat was the only one that I did think will it ever end?" (SU03)</i></p> <p><i>"The faces test, which is the test that's the most useful test to predict the medication, is very long for patients. I get a lot of feedback from people that it's too long" (FG02T1)</i></p> <p><i>"A few of the problems we've had on the ground level is the patients are getting very frustrated with the length of it. We've had quite a few patients complaining at the beginning that they're just fed up doing it" (KI02T1)</i></p>
<p>Difficulties around access and potential exclusion:</p>	
<p>Operational staff and wider informants identified that i-spero was not being used by some service users due to the way mental health symptoms affected their attention and other aspects of cognition, as well as lack of digital familiarity</p>	<p><i>"Some of them are a little bit confused as to why they're looking at faces or what they're supposed to be doing in the test or how it's supposed to help them. I think some of them genuinely don't know why they're doing it. Some of them do have an idea but don't really understand how it's going to help them" (KI06T1)</i></p> <p><i>"The mental state that she was in trying to learn how to use an app. In that state of mind, she would not have been able to do it...I think the app would maybe work for people with mild levels of depression and anxiety, and that are in a place where they have the ability to think straight and be able to utilise something like that." (WS04-05)</i></p>
<p>Compulsory use of technology led to potential exclusion of certain service user groups (e.g. some service users remarked that the interface may be less intuitive for people not used to apps and digital assessments)</p>	<p><i>"I'm nearly 60 but I think somebody who'd be a lot older than me maybe would find that quite difficult, you know, maybe somebody in their 70s or even 80s might find something like that quite difficult" (SU48)</i></p> <p><i>"I'm very lucky I'm of the age that we are used to that level of technology so that was fine. It wasn't anything different to the normal kind of things that you would find in apps and online things in the work place so that was really good" (SU03)</i></p>
<p>Length of i-spero use:</p>	
<p>The majority of service users continued to use the app at the point of the initial call and many were still using it to track change in their depression at six-month follow-up</p>	<p><i>"I use the app kind of weekly or sometimes once a fortnight just to kind of monitor where I am but also what's been really helpful for me is to use it to see because I had to change the medication so I'm now on my third medication. It's just been really useful to see how effective or not effective the medication is" (SU03 at six-month follow-up)</i></p>
<p>At initial interview as well as at six-month follow-up, some service users reported no longer using i-spero.</p>	<p>Ceasing to use i-spero was attributed to log-in issues, access issues, length of assessments or because their symptoms improved to the degree they no longer found the app useful.</p>

	<i>"I'm not really using the online features any more but I am still taking medication [...] I think the app needed some refinement in terms of sort of [...] making it more easy to log in and enter information." (SU01 at six-month follow-up)</i>
<i>i-spero score-based follow-ups:</i>	
Some service users felt that the questionnaire items which determined suicidality alerts did not sufficiently differentiate between suicidal thoughts and suicidal intent	<i>"I guess the only thing would be as sort of a differentiation between that question and 'do you have any intention to harm or kill yourself', because then I think that would definitely require a response from the doctor. But it's possible to think that it would be better if you weren't here without necessarily being suicidal or intending to hurt yourself. So I guess from that respect just making that a bit more, that question a bit more explicit, because every time I filled it in it was like I know in about two hours I'm going to get a phone call. (SU33)</i>
More general follow-up checks based on deterioration of scores were highly appreciated by service users, some of whom felt they would not have shared how they felt without the scores	<i>"So I've had a phone call from her before when she would say "right, how are you?" and I say "fine" and she'll say "well looking at your last test results you don't seem to be feeling fine, do you want to talk to me about that?" [...] So she planned and prepped for that phone call to know that I wasn't alright, and she already knew that so she didn't really have to take my "yeah, I'm fine" for granted because she could rely on another resource" (SU47)</i>

4.3.3. Service user outcomes

4.3.3.1. Comparison of outcomes between groups at six months

Table 7 illustrates that participants in the intervention group exhibited significantly lower depression symptoms when compared to the standard care group after six months of care. No difference in anxiety symptoms nor measurement of changes in service user wellbeing were observed as statistically different between the groups. Differences in severity of suicidal ideation (indicated by responses to question 9 of the PHQ-9 symptom questionnaire) between the groups after six months was of borderline significance ($p=0.053$, Pearson's chi-squared test). A tenth of participants (12.8%, $n=6$) in the intervention group responded as having self-harm thoughts on more than half the days or every day compared to a third (30.0%, $n=12$) in the standard care group.

Table 7: Comparison of service user outcomes between sample groups at Visit 2 (six months)

Outcome measure at Visit 2 (6 months)	Intervention group Mean (SD) (n)	Standard Care group Mean (SD) (n)	p-value (Independent sample T-test)
PHQ-9 total score	11.6 (7.57) (n=47)	14.5 (6.53) (n=40)	0.047
GAD7 total score	9.9 (6.69) (n=47)	11.3 (5.45) (n=40)	0.269
ICECAP-A total tariff	0.693 (0.22) (n=46)	0.622 (0.19) (n=39)	0.122

SD, standard deviation.

4.3.3.2. Service user outcomes over time – intervention group

Table 8 illustrates that participants in the intervention group showed significant improvement in symptoms over time for symptoms of depression (PHQ-9¹³), anxiety (GAD7¹⁴) and wellbeing (ICECAP-A¹⁹). Severity of suicidal ideation as indicated by responses to question 9 of the PHQ-9 symptom questionnaire reduced significantly over time from a baseline proportion of 24.0% of participants (n=20) responding as having self-harm thoughts on more than half the days or every day, to 12.8% (n=6) at six-months post-baseline ($p < 0.001$, Pearson’s chi-squared test). To add clinical context, 35.4% of participants in the intervention group exhibited recovery as defined by reduction in PHQ-9 and GAD7 symptom scores to below clinical case definition (PHQ-9 < 10 and GAD7 < 8) at the six month timepoint³⁹. Clinically relevant improvement was observed for 59.6% of participants in the intervention group, classified as a reduction in PHQ-9 score of 5 points or more³⁹. National NHS targets for IAPT services alone aim for half of service users to be classified as in recovery and two-thirds experiencing reliable symptom improvement after a course of IAPT treatment³⁹. The achievement of these targets vary across the country but have been met³⁹. Reports of improvement from participant interviews gave additional detail about how and why improvement occurred as described in Table 9.

Table 8: Intervention group change in depression, anxiety and wellbeing over time

Outcome measure (n)	Baseline mean (SD)	4-8 weeks mean (SD)	6 months mean (SD)	p-value (repeated measured ANOVA with Bonferroni correction)
PHQ-9 total score (47)	18.3 (5.67)	12.6 (6.61)	11.4 (7.57)	<0.001
GAD7 total score (47)	14.5 (4.50)	10.7 (6.10)	9.9 (6.69)	<0.001
ICECAP-A total tariff (46)	0.570 (0.19)	0.642 (0.18)	0.693 (0.22)	<0.001

SD, standard deviation.

Table 9: Qualitative findings on symptom improvement and wellbeing

Theme	Illustrative quotes and other supporting information
<i>Symptom improvement:</i>	
Most service users reported symptom improvement, as well as an increased sense of wellbeing after attending the clinic.	<p><i>“I’m infinitely better than I was when I first, you know, when I first went in October I was really low and it stayed low for quite a long time, and you know, the last month or so you know, things have really improved” (IDC33)</i></p> <p><i>“Even just playing with my children is much easier because my head’s clearer. I’m not feeling down, you know, as if the world’s crashing in on me. It means that I can get up and face it” (SU69)</i></p> <p>A fluctuation in symptoms during follow up was not uncommon, but many reflected that at six months their symptoms did not worsen and timely help from the clinic usually resulted in improvement.</p>
There was a strong perception by clinic staff that service users improved or recovered at a faster rate than would have occurred without the clinic.	<p>This was in part, due to having a dedicated multidisciplinary service:</p> <p><i>“I would say a majority of the clients that I saw in the clinic that went on to have therapy, probably recovered at a quicker rate...or made some improvements” (KI06T1)</i></p>

	<i>"Because people feel like they are being listened to. That there is this service that really cares about them, and it's there for them. That I think aids their recovery...so I do actually think the clinic does play a role and people feel they are supported and they can be okay" (KI06T2)</i>
While for some, symptom improvement occurred soon after the initial visit to the clinic, for others this was a considerably longer process. In circumstances of worsening of symptoms at six-month follow-up interviews, these were usually temporary and where setbacks occurred, the remote monitoring via the i-spero app was seen as crucial in enabling a timely delivery of care and resulted in a quick recovery	<i>"I unfortunately had a relapse back in December and Dr. [name] at the clinic instantly spotted my scores. I went in that next weekend and she was expecting me because she knew my scores had gone down from looking through the app and she was just absolutely fantastic. She really was brilliant. Really, really supportive and I'm back on a very positive track again" (SU04 at six-month follow-up)</i>
Changes to wellbeing:	
Many participants reported a sense of wellness at the point of the initial interview. They mostly attributed the ability to feel well to the help received at the clinic, suggesting that the clinic was able not only to help with clinical symptom relief, but also meet service user own goals	<i>"Prior to going to the clinic in November, work was my life and it was a case of chucking myself into work, but then I'd come home and I'd just get straight into bed just because I had no motivation to do anything, I wasn't seeing friends, I wasn't seeing family, I wasn't talking to my housemate, it was just a case of just come in, go to bed, get up, go to work. [...] it's [down to] everything that the clinic has given me, but also supported me in being able to engage with again" (SU46)</i>
For many, rather than being symptom-free, being well meant ability to engage in activities meaningful to the individual (e.g. socialise or return to work), as well as being in the moment and ability to enjoy at least some aspects of life	<i>"Being well mean being able to get up without a kind of screaming in your head without having to really talk yourself into the day and it means that I can do the job that I do and operate and...and be in the moment rather than being detached from everything." (SU03)</i> <i>"Still hav[ing] enough energy to live my life. So whether that be through work, energy to go out and exercise...and to literally sort of be with family and friends. Very simple really..." (SU41)</i>
While experiencing some improvement, a small proportion of the interviewees nonetheless felt that this improvement was not sufficient for them to feel 'well'	<i>"I've got a long way to go but I definitely, I'm not at the place where I was when I thought that no-one was going to do anything and that this was all pointless. I'm definitely not at the start of the journey, put it that way, and I think it's just a matter of time and just sticking with it. And it's one of them things, it's not going anywhere anyway, it's going to be with me forever, so I've got plenty of time to master it" (SU47)</i>
Where symptom alleviation was spoken about as the key to wellness, the importance of addressing symptoms remained around being able to engage in everyday life/tasks	<i>"I couldn't drive, I could hardly speak, I couldn't even go to my own house you know I had to stay, I had to be with my mum, and I'm an adult! I couldn't function on my own, I needed somebody to be with me [...] So being well is just, is being able to function day-to-day without having symptoms of anxiety, severe symptoms of anxiety." (SU45)</i>

It should be noted that wider life circumstances played an important role in symptom improvement for a number of participants, including the psychological impact of the COVID-19 pandemic (see section 5.5 for COVID-19 context). While wider individual and societal factors had an impact in symptom improvement or deterioration,

some participants specifically spoke about the clinic – and symptom tracking helping them deal with life circumstances and change.

There was a clear indication that the intervention enabled participants to better manage their symptoms. Figure 6 shows that the use of the i-spero technology supported care management with over half of participants reporting that using i-spero made them feel more confident about the care they were receiving and treatment plan (58.7%, n=27 responding strongly agree or agree). Furthermore, participants valued the ability to use the technology at home but also felt that it was important for them to make time to use i-spero and that this time was not difficult to find in their daily lives.

Figure 6: Service user experience of i-spero in supporting care and management of symptoms.

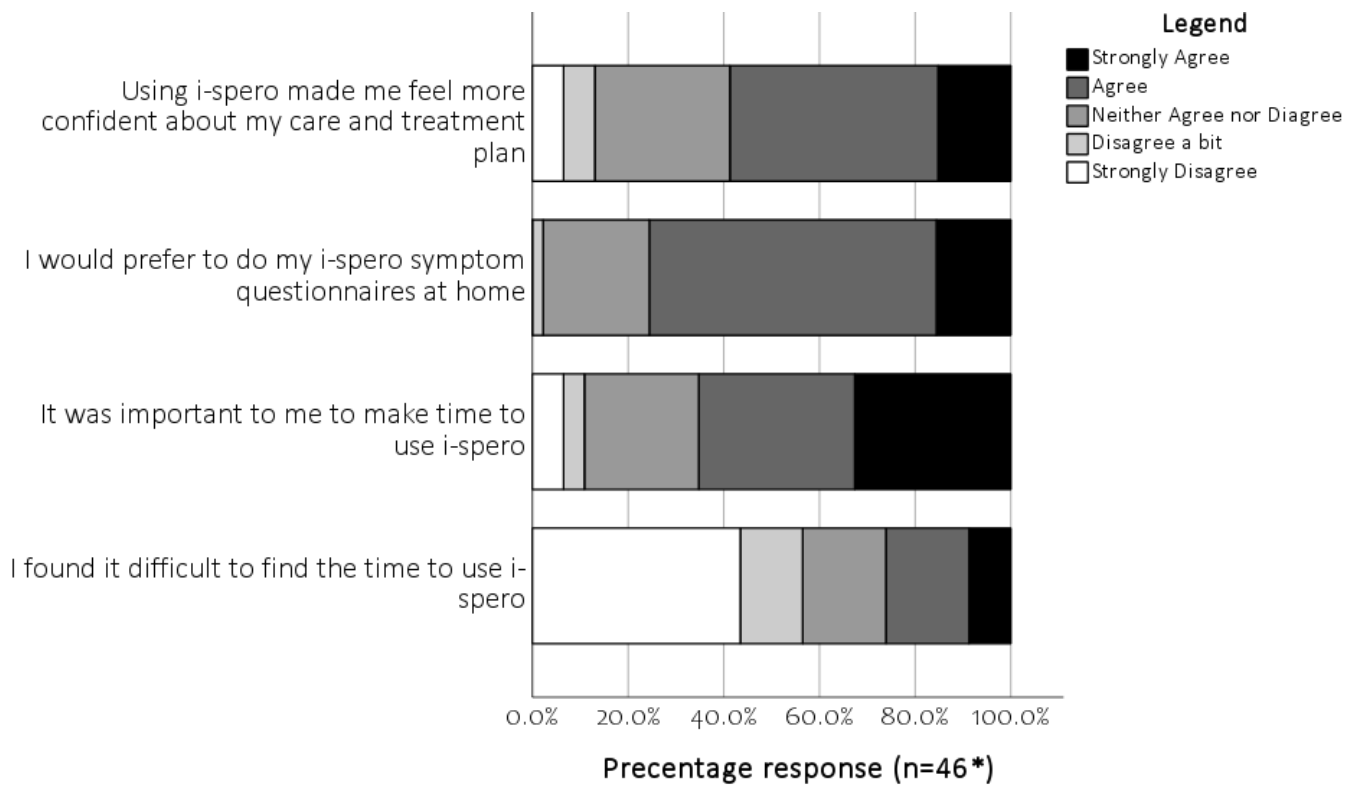


Figure 6 shows the responses to a service experience questionnaire completed by participants in the intervention group at the 6-month visit. *Total respondents to each question is n=46, except for the question relating to use of i-spero technology at home where the sample total is n=45. Data relating to the questions asked on the y-axis are displayed with respondents asked to answer whether they Strongly agree, Agree, Neither Agree nor Disagree, Disagree a bit or Strongly Disagree.

Participants in the intervention group reported statistically significant ($p=0.011$) improvement in joined up support and care (84.8%, n=39 answering sometimes or always experiencing joined up care in the LTC-6 questionnaire at the six-month time point) compared to the control group (65.8%, n=25). The majority of participants specifically related an improvement in depression (and/or anxiety) symptoms to the holistic, multifaceted help they have received from the clinic.

Approximately two-thirds (60.9%, n=28) of the intervention group participants felt more supported to manage their own health in comparison with 18.4% (n=7) of the standard care participants ($p=0.001$) after six months of care. Despite feeling more supported, there was no change in how confident participants felt about managing their own health ($p=0.357$) with 71.7% and 67.6% of participants responding that they were somewhat or very confident in the intervention group and standard care group, respectively. Similarly, no difference in samples was observed when participants were asked if they were involved as much as they wanted to be in decisions about their care between groups ($p=0.168$). Those in the intervention group did experience better discussions with clinic staff about the most important elements for managing their own health ($p<0.001$) and had better experiences of receiving enough information to help them manage their health when compared to standard care group responses ($p=0.017$). Table 10 shows qualitative data supporting the participants' sense of improved management.

Table 10: Qualitative findings on clinical management and self-management

Theme	Illustrative quotes and other supporting information
<i>Clinical management and self-management:</i>	
Service user participants frequently spoke about how the clinic helped them to self-manage their anxiety and/or depression and identified that having a choice of treatment options, seeking and taking up help offered in a timely manner and agreeing a plan of action on how to monitor illness progression were important	<p><i>"[W]hen I first went I was very like uncertain and unsure and I didn't know where I was going or what I needed. Where as now I know I just need sort of like...a little call from the doctor every now to make sure my meds are ok. And apart from that I'm all right now" (SU29)</i></p> <p><i>"I think it's because it's been, you know, regular appointments and regular check-ins, so an element of self-stuff, but I think also it's down to the fact that you've been seeing, and often seeing the same doctor which is helpful, you know, several times over a reasonably short period rather than just going back every six months or so" (SU33)</i></p> <p><i>"[T]hey also made me do things for myself. I wasn't just led. I know I said I like being led but I know that that's actually not a good thing you have got to take charge of your own life and they encourage you, and the little book they give you to say this is what I've done today or this is..." (SU36)</i></p>
Clinic staff particularly related the experience of using i-spero as supporting clinical management effectively	<p><i>"The PReDicT test is really useful because I think it absolutely does mean that we titrate medication differently so for me that's obviously the big selling point with the tech but I actually do think that actually people do the questionnaires and you can see the results and their doing them in their own time at home is a very efficient way to deliver care" (FG02T1)</i></p> <p><i>"It really guides your prescribing when you see their scores, and it guides the, it guides the titration of medication based on the PReDicT test, so without it it's so hard to do it" (KI01T1)</i></p> <p><i>"From a GP perspective, I think the apps brilliant and I think in terms of medication, monitoring, and seeing what the impact of any medication is having" (WS04-05)</i></p>

Over the follow up period, a total of 179 i-spero alerts were dealt with by the practice outside of the intervention clinic (Table 11). Two thirds of service user participants triggered a maximum of one symptom deterioration alert (PHQ-9 or GAD7 related) from the i-spero system that was acted upon by the clinical staff by either increasing medication dose, changing medication or a clinical review over the phone. Only one third of participants triggered

a suicidality alert; however, one service user triggered 13 suicide alerts alone. Qualitative data (Table 12) showed that although alerts were viewed as positively assisting with proactive management, they added additional clinical burden.

Table 11: i-spero alerts triggered by participants and sent to the practice for clinical action during the participant follow up period of six months.

Type of alert	Number of alerts from individual service users to the GP practice, n (%)			Max alerts by any one service user (n)	Total alerts from all service users (n)
	0	1	2 or more		
Suicidal ^a	66 (79.5)	8 (9.6)	9 (10.9)	13	62
PHQ-9 deterioration ^b	25 (30.1)	58 (69.9)	0 (0.0)	1	58
GAD7 deterioration ^b	24 (28.9)	59 (71.1)	0 (0.0)	1	59
Total alerts					179

^asuicide alerts are based on service user scores on Q9 of PHQ-9 answering nearly every day or thoughts of death or suicide within the QIDS-SR16 questionnaire of the PRedICT test,

^b PHQ-9 or GAD7 deterioration alerts are based on a reduction of <50% in scores recorded four weeks (or nearest score) after the first care plan added service.

Table 12: Qualitative findings on alerts

Theme	Illustrative quotes and other supporting information
Alerts:	
The alerts sent by the i-spero technology, including those triggered by symptom deterioration but more importantly the suicide alerts, were seen as positive in terms of being able to deliver pro-active care. However, the volume and non-specificity of suicide alerts was also seen by some as a nuisance, adding to workloads	<p>“So the service allows us to be a lot more proactive, so you’ve got the reminders from the technology which are pinging up...,so we call them proactively” (K101T2)</p> <p>“Unless someone actively phoned us to say that they were suicidal, we would never have known that and therefore we would never have managed that. Now, I think the fact that we do know that and we can give someone a call is a good thing and maybe is something that you would hope we should be doing anyway” (K103T2)</p> <p>“I think by having technology like this it does...it flags all our alerts. Now, that increases contact because I have to ring someone if I get at alert but does that mean that they then go and have an admission because they going to attempt suicide” (K101T2)</p>

4.4. What are the components of the care delivery model that are really making a difference?

Seven key components or ‘active ingredients’ were identified that supported service provision, set out in Figure 7. These are expanded upon in Table 13 below, which draws on qualitative data to illustrate the themes.

Figure 7: Active ingredients for the success of the care delivery model

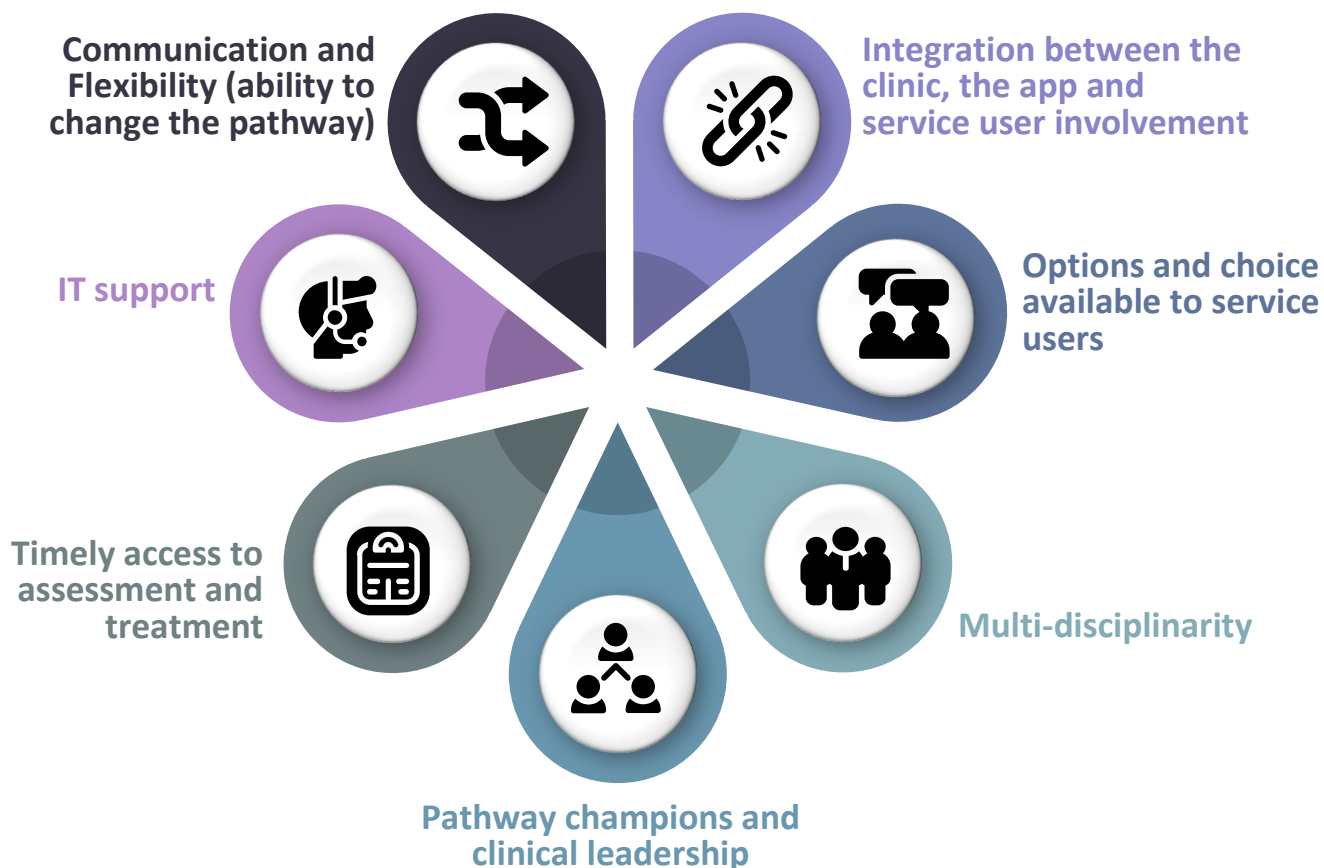


Table 13: Active ingredients of the service supporting implementation and outcomes with evaluation evidence.

Component	Illustrative quotes
Integration between the clinic, the app and service user involvement provided more holistic care and guided clinical management	<p>“The service provider, the service user and the technology together provide you with that glue and that integration that provides a more holistic, rounded management of care that, you know, can’t be done without those three things together” (WS01)</p> <p>“I really do like the technology, I find it really helpful to use alongside speaking to people, I think generally people feel, I think they really like it, I think they like monitoring themselves as well, it’s a positive thing” (KI01T1)</p> <p>“What’s good about it is, it isn’t just technology, you’re talking about technology complimenting a consultation” (WS08)</p>

	<p><i>"From a GP perspective, I think the apps brilliant and I think in terms of medication, monitoring, and seeing what the impact of any medication is having" (WS04-05)</i></p> <p><i>"It really guides your prescribing when you see their scores, and it guides the, it guides the titration of medication based on the PReDicT test, so without it it's so hard to do it" (K101T1)</i></p>
<p>Options and choice available to service users at the clinic resulted in positive experiences</p>	<p><i>"I just felt that I wasn't just left with a prescription and off you go...sort of deal with it. I very much like ok we want to assess you in four weeks' time. We want to get the counseling started and then, only then are we happy to just...not letting you go but just sort of watch you." (SU41)</i></p> <p><i>"They definitely met my needs. [...] in the past I hadn't had positive experiences with that and they were very quick to reassure that look, you know, give this a go and if it's not working we can then very quickly change things up, so it was that notion of continuous care I think that was the thing that really sold me on it" (SU59)</i></p> <p><i>"[T]he first person you speak to is the doctor and she said she would advise it might be helpful for you to see this person but you could see this person if you wanted to and explained what they did and then you'd get the choice of saying no I don't think that would be useful either and that sort of thing" (SU05)</i></p>
<p>The multi-disciplinarity and team approach and skill mix of professionals with an interest in mental health</p>	<p><i>"Well from one room to another between the three different disciplines if that's the right word [...] So I felt that I was getting someone's complete attention who understood the nuances of my condition and had the time to think about it if you know what I mean. I think that worked" (SU20)</i></p> <p><i>"I don't really know what other professionals there could potentially be. As far as I'm aware you can go down the anti-depressant route, you can go down the talking therapies route or both like I've done and I...I wouldn't know what else to expect. I wouldn't know who else would be there...so, everyone who's there is brilliant and they're doing their job" (SU04)</i></p> <p><i>"We've got lots of clinicians, patients generally see a different clinician every time and quite often generally mental health isn't the interest of many clinicians so it's in and out, whereas you know, myself and [name] have got a lot of interest in it so you get more empathy, and I think those normal surgeries, they don't have that feeling of it's a clinic just for their condition" (K108T2)</i></p> <p><i>"Dr. [name] is clearly very passionate about supporting peoples mental health and wellbeing and is prepared to put the time into enable that to happen and I think that that's one of the reason why the clinic is so successful is that feeling of actually being really listened to and being really understood and then having that follow up at the time they said that it was going to happen just makes you feel a bit more worthy" (SU03)</i></p>
<p>Pathway champions and the effective clinical leadership as a driving force for the service</p>	<p><i>"Because of their championship and leadership it has been relatively easy to actually get it implemented, up-and-running and being used (WS01)</i></p> <p><i>[The] overall experience has been very positive in terms of the team, I think everybody's worked really well together, great leadership, everybody's very supportive (WS01)</i></p> <p><i>"Having those champions within the GP setting I think is critical for it to be able to work... having a champion I think is key" (K102T2)</i></p>
<p>The clinic structure provided more timely access to assessment and treatment</p>	<p><i>"I think a lot of people who are feeling anxious or feeling low or depressed they're not quite...they don't want to make phone calls they don't want to reach out. But being able to have a walk in clinic where you can just amble in there and go actually I'm not feeling very well. That, just being able to do that I think is amazing" (SU17)</i></p>

	<p><i>"I was able to just go when I felt I needed to as opposed to if you feel you need to and then the appointment sometime away whether that's an hour away or a day away or a week away it's not necessarily getting to you when you need it. I think that was important" (SU20)</i></p> <p><i>"[It] is quite nice in that I don't have to book an appointment and see a GP and feel that I'm wasting their time by booking an appointment and then having to wait etc. It's quite nice that you can just walk in if I wanted to. Equally I don't have to if I don't want to" (SU05)</i></p> <p><i>"The normal wait is six to twelve weeks. Sometimes so you can go away from a GP and know that you've still got another two months wait before they're even going to see a counsellor" (K102T2)</i></p>
<p>IT support was vital to overcome initial technical problems</p>	<p><i>"We provided a live help desk availability so we actually had people here in Pivotal working on a rota shift on the Saturdays to provide telephone support for any sort of emergency issues, any emergency, I know certainly for the first, for 2 to 3 weeks we actually had somebody from Pivotal in person at the clinic, so I think that really helped provide confidence for everybody in terms of making sure that the software did work... because of that live support that was provided right at the beginning, you know, if there were any issues or clarifications they were sorted out very quickly" (WS10)</i></p> <p><i>"The Saturday support was no longer required, you know, there was often many Saturdays where we had no calls at all [to the i-spero helpdesk]. I think for the last few weeks of that Saturday support there was hardly a call made, which was good, which meant that the clinic was running smoothly and the software was running smoothly" (WS10)</i></p>
<p>Communication and flexibility of the service design enabled improvements to be made when necessary</p>	<p><i>"I think it's fantastic. I think it's just from a service point of view. I think it's just taken a little bit of time to embed the pathway in a way that actually works" (WS04-05)</i></p> <p><i>"I wanted to make the social prescribing more depression anxiety related, as opposed to just general social prescribing, so originally we were talking about smoking cessation and weight loss, they were quite there in their social prescribing mindset. Some of the things that we discussed were around it very much being mental health social prescribing, so they definitely had the, they took that onboard in their approach and they changed the people delivering it, and their approach has definitely improved and they were utilising like the Umbrella Centre, they were utilising Visit Gardens, so using some of the Mind stuff within the community much better" (K101T1)</i></p> <p><i>"So I think in terms of that initial phase and that initial rollout, I think it was very positive and I think we've had good communications between us all, in terms of the regular meetings that we have, the quarterly meetings and the regular updates that we have between us to understand how the clinic was working, how certain processes and methods could be improved to provide greater efficiency ..." (WS10)</i></p> <p><i>"I think one of the big things was the i-spero application was designed around being a patient application but what we found increasingly was that because of various situations, it would help the efficiency of the clinic sort of allowing the GP to edit certain things on behalf of the patient, so one of the things that was flagged was the ability to edit and update care plans on behalf of the patient" (WS10)</i></p> <p><i>"The patients actually wanted to see the score and so the clinicians thought it was a good idea for the patients to see that and so we implemented an update there" (WS10)</i></p>

4.5. How have contextual factors affected implementation and outcomes?

A number of local and national factors were perceived to influence implementation and sustainability. Table 14 uses qualitative data to set out the identified contextual factors that had a significant impact on the delivery and implementation of the new service pathway. These contextual factors also consider elements that impacted on participants and their outcomes.

Table 14: Contextual factors affecting service implementation and outcomes

Description of context and impact	Evidence
<p><u>Commissioning landscapes:</u> Changes to the commissioning landscape, with respect to the merger of Commissioning Groups in Kent and Medway, caused concerns about the sustainability of the service in the long-term. Having Commissioner representatives involved in the design of the new service at the start, sitting on the project steering committee and linking to mental health commissioners in particular helped ensure the outcomes of the new service remained centre-stage.</p> <p>The different geographical service footprints limited the reach of services within the clinic e.g. IAPT service footprint. Also, the fact that the service was limited to two medical practices meant it could not be offered to all service users within the larger region resulting in a '2-tier' service as highlighted by wider stakeholders. Service provision boundaries is something that would have to be addressed for scalability.</p>	<p><i>"It's now being approved going to Kent and Medway as a CCG so that completely changes our footprint now...we're slightly further removed but...I think we've got it on the agenda when we needed to so I think it's there. We have the CCG link worker on the steering committee" (FG02T1)</i></p> <p><i>"I think the biggest problem is this is just Newton place and Faversham Medical Centre taking part and we operate in Swale as well which doesn't include those. So first, it's very limited because we can only use it for those particular clients" (WS06-07)</i></p>
<p><u>Primary care service demand:</u> Demand in the system for primary care and other services created problems for delivery.</p>	<p><i>"We are getting more and more people register everyday with us. We're not getting any more staff so it's generally just something we're facing as a surgery anyway...the clinic hasn't increased that a massive amount...in the grand scheme of things it's not a lot when actually we're sort of completing fifty registration forms a week anyway for [new] patients" (KI02T2)</i></p>
<p><u>Demand on regional mental health services:</u> High demand on regional mental health services impacted on the ability to recruit a Clinical Psychiatric Nurse which was felt to be an important addition to the specialist skills within the clinic and meeting needs.</p>	<p><i>"Finding a CPN has been an issue so getting the staff we originally wanted has not worked and I think we've had a lot of conversations we've tried everything but there just isn't the CPNs around or people that want to do it so that obviously has impacted" (FG02T1)</i></p>
<p><u>BREXIT:</u></p>	<p><i>"I know the Brexit situation has been kind of discussed in the surgery between different teams and different staff but it could potentially have an impact on us...because Faversham is under the...I can't remember the name...the plans around the motorways... so we don't</i></p>

<p>More broadly, Brexit created a high degree of uncertainty in terms of staffing and maintaining the service.</p>	<p><i>know how that's going to affect staffing or anything else actually at this point" (K106T1)</i></p>
<p>Severity of service user presentation : The majority of service users presenting were experiencing moderate or severe depression. This put more demand on GPs within the intervention which was not intended originally. The level of severe depression impacted on staff time, intervention costs, emotional burden for staff and service user readiness to engage in services. As a result the service had to adapt quickly.</p> <p>Evidence suggested there was an opinion that mental health needs were not being met locally, particularly those with severe anxiety or depression not getting the help they needed from current mental health services so the clinic provided a vital service.</p>	<p><i>"I definitely think we're still getting quite the severe ones and I think that's because there's just a lack of community mental health services available so these patients are just getting lost. And so, because we're giving them that dedicated time, they've got some wrap-around care, they've got the app to support them... So I think they've fallen through the gap and I think this has just provided that bridge between standard primary care and community mental health team. Which is why I think, actually, we've probably got quite a lot of the severe coming through. But mental health services are just poor, they're so poor locally and it shows it, I think" (K102T1)</i></p> <p><i>"There were some clients who genuinely, probably should be under secondary care services. So for those ones, it was a case of I had to try and grab a GP where I can and ask them to refer because we don't technically really refer to secondary care services anymore. That has to be the GP. So it kind of felt a little bit like oh, am I wasting the client's time here. Now they've got to wait around and see the GP and I've got to ask the GP to do this. And I felt like there wasn't really a structure in place for clients that were probably above the expectation" (K106T2)</i></p>
<p>COVID-19: Unsurprisingly, the Covid-19 pandemic had a significant impact on the delivery of the clinic. The number of referrals to the clinic saw an initial drop due to fewer contacts between clinicians and people with mental health needs. This resulted in reduced waiting times for those willing to engage with some services within the clinic, e.g.IAPT, during the pandemic. Use of i-spero was particularly helpful for remote consultations. The shift to telephone appointments as a result of COVID was not deemed preferable for service users. Service users felt the clinic offered a life-line during the COVID-19 period.</p> <p>As a result of this shift to remote consultation, we looked at changes in the number and type of appointments before and after the onset of COVID-19.</p>	<p><i>"In terms of our waiting list as an IAPT service, people are actually being seen quicker than they were. Because where everyone's working remotely at the moment, it seems like being able to fit people in because we're not relying on room space, or we're relying on you know, therapists traveling in between locations and stuff like that" (K106T2)</i></p> <p><i>"In this world with all the remote stuff, it's [i-spero] even more helpful, so you can't see the patient, but actually I can see their scores, and I can see how things have been running, and so it's easier to do a telephone consultation when you've got all that information, it's hard to do a consultation without it" (K101T2)</i></p> <p><i>"No, it's definitely all down to the clinic and the offers available to me. And I think certainly without all of that that I've had with COVID-19 with the job loss with the half out of work now; we've had to cancel our wedding that we've been planning for three years, I think I would have reached an all time low. So, the first week of all this starting yes, I was very anxious, but I never had the attack because it was almost like, I knew I was getting that questionnaire and I knew that the results would give me an indication of what I needed. So, no, it's been great for me" (SU71)</i></p> <p>Aligning with the government timelines whilst being considerate of the progression of those using the new service (i.e. just started using the service or using it for a while), we defined the following periods: (a) pre-lockdown (1st January 2020-15th March 2020) and (b) lockdown (16th March 2020-31st July 2020), the latter extended to</p>

	<p>the end of July to account for those shielding. In the pre-lockdown period, 71 appointments were recorded in total for those in the intervention group. Of these, 57 (80%) were with a GP, 2 with a nurse practitioner (3%) and the remaining 12 (17%) with OneYou services. In the lockdown period, 42 appointments were recorded in total for those in the intervention group, primarily with a GP (88%) and a few (12%) with a nurse practitioner. Overall, 32% of appointments took place over the phone in the pre-lockdown period compared with 90% during lockdown. Interestingly, appointments lasted about three minutes longer, on average, prior to lockdown than during lockdown. However, this duration also includes the time taken to type notes, which may not be an accurate reflection of the actual service user contact time. In cost terms, assuming that a GP phone consultation costs 40% less than a face-to-face consultation²⁹, this would translate to a total cost of £1,908 for all GP consultations pre-lockdown compared to £697 during lockdown, equivalent to a reduction of £1,222.</p>
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4.6. How have changes to resources/activity impacted costs?

4.6.1. Saturday clinics

In the intervention group, 288 Saturday appointments were recorded in total, of which 197 (68%) were with a GP, 36 (13%) with OneYou and 55 (19%) with IAPT. GP appointments lasted 17 minutes on average which was significantly longer than OneYou and IAPT appointments (9 and 10 minutes respectively). This is not surprising, however, as GPs were the main point of contact when the service user firstly attended the Saturday clinic – they were responsible for assessing the service user’s depression severity and for triaging them to the relevant services. Each time a service user presented at the clinic, they saw one health professional on average, which does not necessarily imply that the remaining services were not offered to them on the day. Instead, it may be that either due to time constraints (for example, clinic ran for half a day) these appointments were scheduled for the following Saturday or another day during the week or that it was just a follow-up appointment. Indeed, for some service users only an IAPT, OneYou or GP appointment (latter over the phone) was recorded on a Saturday. Overall, an appointment was recorded on three Saturdays on average per service user. Table 15 shows the average cost of each of the different components that were used to calculate the cost of Saturday clinics. These are only applicable to the intervention group.

Table 15: Average costs of Saturday clinics (intervention group)

Costs (£)	Mean (SD)	Min.	Max.
Reception	60.64 (43.35) ²	7.73	246.12
Management	12.18 (10.98)	0	55.28
GP	57.92 (38.29)	0	222.84
Nurse ¹	n/a	n/a	n/a
IAPT	13.91 (18.31)	0	60.76
OneYou	7.29 (19.23)	0	109.74

Additional costs associated with:

Reception (overtime)	2.97 (2.07)	0.50	11.64
Management/Management admin/GP sessions	51.94 (35.52)	11.99	222.67

n/a, not applicable; SD, standard deviation; Min., minimum; Max., maximum. ¹ No Saturday appointments with a nurse were recorded in the health economics study sample. ² We were unable to separate the actual reception time spent on running the Saturday clinic from the time spent on other research activities, thus this may be an upper bound of the true reception time.

4.6.2. Health and social care resource use

Table 16 shows the average resource use per service user in each group observed in the data for **the complete cases only** (i.e. 40 service users in the standard care, group; 44 service users in the intervention group). Participants in both study groups had one GP appointment on average at six months. This did not include contact with professionals responding to i-spero deterioration or suicidality alerts which were not included in this analysis. Amongst all community-based services, and perhaps not surprisingly given the nature of the study participants, talking therapy was most frequently used amongst both study groups, with participants in the intervention group reporting five appointments on average at six months compared to three reported by those in the standard care

group. The use of support or self-help groups was also reported, albeit somewhat less frequently by those in the standard care group. Any further conclusions should be tempered given that very little was reported in the follow-up assessments.

Table 16: Average resource use per participant by study group (complete case)

Service Mean (SD), min-max	4-8 weeks Intervention group (n=44)	6 months Intervention group (n=44)	6 months Standard Care group (n=40)
Primary care			
GP (face-to-face/phone)	2.22 (2.11), 0-8	1.23 (2.06), 0-9	0.97 (1.51), 0-7
Nurse practitioner	0 (0), 0-0	0.07 (0.25), 0-1	0.10 (0.30), 0-1
Mental health worker/nurse	0 (0), 0-0	0 (0), 0-0	0.05 (0.32), 0-2
OneYou	0.48 (1.05), 0-3	0.25 (0.69), 0-3	0 (0), 0-0
Community-based			
Community mental health centre	0.18 (0.50), 0-2	0.27 (0.95), 0-4	0.08 (0.35), 0-2
Group therapy	0 (0), 0-0	0 (0), 0-0	0.08 (0.47), 0-3
Talking therapy	1.30 (2.25), 0-11	5.39 (6.75), 0-30	3.13 (6.10), 0-26
Social care-based			
Occupational therapy	0.11 (0.44), 0-2	0.02 (0.15), 0-1	0 (0), 0-0
Service user support or self-help groups	0 (0), 0-0	0.52 (2.03), 0-10	0.05 (0.22), 0-1
Dietitian	0 (0), 0-0	0.05 (0.30), 0-2	0 (0), 0-0
Hospital-based (inpatient)			
Acute psychiatric ward	0.23 (0.15), 0-1	0 (0), 0-0	0 (0), 0-0
Psychiatric emergency/intensive care/crisis centre	0.05 (0.21), 0-1	0.02 (0.15), 0-1	0.03 (0.16), 0-1
Hospital-based (outpatient)			
Psychiatrist	0.23 (1.51), 0-10	0.11 (0.49), 0-3	0 (0), 0-0
Occupational therapist	0 (0), 0-0	0.02 (0.15), 0-1	0 (0), 0-0

SD, standard deviation; Min., minimum; Max., maximum.

Note: The following services were not reported by any of the service users: day care centre (community-based), social worker (social care-based), psychiatric rehabilitation ward (hospital-based, inpatient), psychiatric long-stay ward (hospital-based, inpatient), psychologist (hospital-based, outpatient).

Mean health and social care costs broken down by type of service, study group and for each time point are presented in Table 17. With or without imputation, health and social care services costs are significantly higher for the intervention group than for the standard care group at six months, which is consistent with more frequent use of related services by the intervention group in the same period, discussed earlier on the reported resource use. There are no significant differences in hospital services costs and medication costs between the intervention and standard care group. Looking at differences in medication costs over time, it seems that in the intervention group stronger and/or more diverse medication was prescribed within eight weeks, as the medication costs were almost eight times higher on average during that period than at six months. This may also coincide with severely depressed respondents presented in crisis at the clinic who improved significantly at six months.

Table 17: Average health and social care costs by study group

Costs (£)	4-8 weeks Intervention group (n=44)	6 months Intervention group (n=44)	6 months Standard care group (n=40)
<i>Before imputation</i>			
Health and social care services costs (excluding costs of Saturday clinics)			
Mean (SD)	195.65 (181.72)	396.01 (422.01)	230.88 (378.83)
Min.	0	0	0
Max.	933.00	1,683.00	1,458.60
Hospital services costs			
Mean (SD)	25.96 (123.08)	11.99 (40.92)	5.53 (35.00)
Min.	0	0	0
Max.	690.55	221.35	221.35
Medication costs^a			
Mean (SD)	16.85 (78.51)	2.50 (2.13)	3.08 (3.38)
Min.	0	0	0
Max.	490.84	11.24	10.65
<i>After imputation</i>			
Health and social care services costs (excluding costs of Saturday clinics)			
Mean (SD)	198.61 (178.10)	286.04 (366.07)	230.88 (378.83)
Min.	0	0	0
Max.	933.00	1,683.00	1,458.60
Hospital services costs			
Mean (SD)	18.05 (98.21)	7.72 (32.78)	5.53 (35.00)
Min.	0	0	0
Max.	690.55	221.35	221.35
Medication costs^a			
Mean (SD)	19.89 (96.40)	2.27 (1.99)	3.08 (3.38)
Min.	0	0	0
Max.	625.61	11.24	10.65

SD, standard deviation; Min., minimum; Max., maximum.

^aMedication costs in the intervention group were not imputed.

^bOne service user was excluded from the imputation analysis as they reported unrealistic resource use (e.g. 200 talking therapy appointments) within the first follow-up assessment timeframe.

^cCosts in the standard care group were not imputed.

The total costs to the health and care provider (NHS) before and after imputation are shown in Table 18. They comprise the total health and social care services costs, total hospital services costs, total intervention costs and total medication costs. In detail, the average total costs for the use of health and care services (before imputation) are £591.66 (SD £519.19) for the intervention group compared with £230.88 (SD £378.83) for the standard care group. In addition, the average total costs for the use of hospital services are not significantly different between the study groups (£37.95 (SD £149.48) in the intervention group versus £5.53 (SD £35.00) in the standard care group). The mean total costs of any antidepressant medications are significantly higher (at the 5% significance level) for the intervention group (£19.35 (SD £78.08)) compared with the standard care group (£3.08 (SD £3.38)).

The costs of Saturday clinics, higher total health and social care services costs and medication costs are likely to drive the total costs to the NHS for the intervention group. Pragmatically, the mean total costs to the NHS (before imputation) are £895.04 (SD £580.17) for the intervention group and £239.49 (SD £387.34) for the standard care group. The patterns remain even after imputing for the missing cost data in the intervention group. Mann-Whitney tests show the average total NHS costs to be significantly different (at the 1% significance level) between the study groups before and after imputation.

Table 18: Total NHS costs by study group

Costs (£)	Intervention group (n=44)	Standard care group (n=40)	p-value (Mann-Whitney test)
<i>Before imputation</i>	Mean (SD), min-max	Mean (SD), min-max	
Total NHS costs (including cost of Saturday clinics)	895.04 (580.17), 105.71-2730.08	239.49 (387.34), 0-1463.89	<0.001
Total costs of Saturday clinics	231.13 (129.44), 51.24-801.95	n/a	n/a
Total health and social care services costs (excluding cost of Saturday clinics)	591.66 (519.19), 0-2541.24	230.88 (378.83), 0-1458.60	<0.001
Total hospital services costs	37.95 (149.48), 0-737.47	5.53 (35.00), 0-221.35	0.120
Total medication costs ^a	19.35 (78.08), 0-490.96	3.08 (3.38), 0-10.65	0.021
Costs (£)	Intervention group (n=70)^b	Standard care group (n=40)^c	p-value (Mann-Whitney test)
<i>After imputation</i>	Mean (SD), min-max	Mean (SD), min-max	
Total NHS costs (including cost of Saturday clinics)	756.00 (511.69), 105.71-2730.08	239.49 (387.34), 0-1463.89	<0.001
Total costs of Saturday clinics	208.91 (125.48), 38.05-801.95	n/a	n/a
Total health and social care services costs (excluding costs of Saturday clinics)	484.65 (448.92), 0-2541.24	230.88 (378.83), 0-1458.60	<0.001
Total hospital services costs	25.76 (119.49), 0-737.47	5.53 (35.00), 0-221.35	<0.001
Total medication costs ^a	22.16 (96.40), 0-629.80	3.08 (3.38), 0-10.65	0.076

SD, standard deviation; n/a, not applicable; Min., minimum; Max., maximum.

^aMedication costs in the intervention group were not imputed.

^bOne service user was excluded as they reported unrealistic resource use (e.g. 200 talking therapy appointments) within the first follow-up assessment timeframe.

^cCosts in the standard care group were not imputed.

4.6.3. Sensitivity analyses

In sensitivity analyses, we considered two other cost scenarios. In the first scenario, we assumed that there is a different unit cost for face-to-face and telephone consultations taking place during the week (i.e. a telephone consultation costs 40% less than a face-to-face consultation) following limited research evidence on this topic²⁹. In the second scenario, we assumed that the practice staff are familiar with the new service, and that the support provided to run the Saturday clinics by reception/admin was nine hours per week, management staff was one

hour per week and a fixed i-spero fee of £2.50 for each service user. Total NHS costs from the sensitivity analyses are very similar to what was presented in the main analysis (see Table 19 for more details).

Table 19: Sensitivity analyses

Costs (£) Before imputation	Intervention group (n=44)	Standard care group (n=40)	p-value (Mann-Whitney test)
Cost scenario 1			
Total NHS costs (including cost of Saturday clinics)			
Mean (SD)	871.30 (570.72)	236.69 (387.24)	<0.001
Min.	105.71	0	
Max.	2,697.44	1,463.89	
Cost scenario 2			
Total NHS costs (including cost of Saturday clinics)			
Mean (SD)	887.09 (583.75)	239.49 (387.34)	<0.001
Min.	90.06	0	
Max.	2,731.11	1,463.89	

SD, standard deviation; n/a, not applicable; Min., minimum; Max., maximum.

4.6.4. Additional analysis

In an additional analysis (Table 20), we accounted for the limited out-of-pocket expenses and loss of earnings reported by the service users in each study group to capture the societal perspective. Both loss of earnings and out-of-pocket expenses vary substantially from one service user to another, as indicated by the large standard deviations. Service users in the intervention group reported significantly higher out-of-pocket expenses (e.g. parking tickets, prescription charges) than those in the standard care group, which is not surprising given the more frequent use of services and higher medication costs for this group. Total NHS costs remain significantly different (at 1% significance level) between the study groups as indicated by the results from the Mann-Whitney test.

Table 20: Additional analysis (out-of-pocket expenses and loss of earnings)

Costs (£) - societal	Intervention group (n=44)	Standard care group (n=40)	p-value (Mann-Whitney test)
Total loss of earnings			
Mean (SD)	3,143.18 (14,282.24)	728.75 (2,492.91)	<0.524
Min.	0	0	
Max.	88,300	15,000	
Total out-of-pocket expenses			
Mean (SD)	155.61 (698.46)	17.76 (49.51)	0.002
Min.	0	0	
Max.	4,593	248	
Total NHS costs (including cost of Saturday clinics)^a			
Mean (SD)	4,193.84 (14,929.80)	986.00 (2,724.05)	<0.001
Min.	105.71	0	
Max.	93,655.59	16,658.41	

SD, standard deviation; n/a, not applicable; Min., minimum; Max., maximum.

^aBefore imputation. They include total NHS costs (including cost of Saturday clinics), out-of-pocket expenses and loss of earnings.

4.6.5. Cost-effectiveness

The intention is not to report results from an in-depth cost-effectiveness analysis. Instead, we will only attempt to calculate the ICER by looking further at differences in QoL, and subsequent QALYs between the study groups. Given the strict assumption with regards to the QoL of service users in the standard care group at baseline, it would be sensible to only present average QoL scores at six months for each group. These are shown in Table 21 together with estimates of QALYs (after imputation of missing QoL scores). Health-related QoL of service users at six months is slightly higher for those in the intervention group than in the standard care group, however, the difference is not statistically significant. The picture is similar for the QALYs – service users in the intervention group gained 0.007 extra QALYs, which is equivalent to an extra 2.6 days at full health, than those in the standard care group. However, the incremental effectiveness (i.e. difference in QALYs between the two groups) remains not statistically significant. The attempt to calculate an ICER (i.e. ratio of incremental costs over incremental effectiveness) could give an indication of whether the new service is likely to be cost-effective or not. For given incremental costs and incremental effectiveness as described above, the ICER in this case would exceed the recommended national threshold range (£20k-£30k) making the new service unlikely to be value for money. However, we should avoid any further conclusions given the sample size caveats and limited reported resource use highlighted in this analysis.

Table 21: Mean QoL scores and QALYs by study group

After imputation	Intervention group (n=70)	Standard care group (n=30) ^a	Difference (p-value) ^b
QoL score at 6 months			
Mean (SD)	0.628 (0.251)	0.567 (0.245)	0.262
QALYs			
Mean (SD)	0.303 (0.108)	0.296 (0.062)	0.743

SD, standard deviation.

^aTen service users were excluded from the standard care group sample as they could not be matched to those in the intervention group to obtain a QoL score at baseline.

^bDifference: intervention group versus standard care group. Reported p-values are from the t-test of the difference.

Qualitative data provided additional insight into the changes in resources as a result of the intervention as outlined by Table 22:

Table 22: Qualitative interview findings on cost-effectiveness

Component	Illustrative quotes
There was an acknowledgment that running the clinic was expensive largely due to overheads and staff costs, especially on a Saturday.	<p>“It does increase overheads having to have the building open especially for the Saturday clinic where as if we could bring it into the week the surgery is already open, we’ve already got staff working so that would massively reduce the costs and then the patients would still get the benefit of that service” (KI02T2)</p> <p>“By having a walk-in clinic on the Saturday morning, that is a cost, an additional cost that probably is going to be difficult to justify in terms of the value that you’re going to gain from this...My worry is that because of the added resource, rather than just using existing resources more effectively, will increase the cost and that will make it be cost prohibitive for adoption is my worry” (WS01)</p>

	<p><i>"It costs because we have a member of staff or somebody who's working on Saturday, which takes them away from the week working because obviously they need that time... that's about the only issue in terms of time cost effectiveness that I can see"</i> (WS06-07)</p>
<p>The number of service users seen in the clinic was seen as sub-optimal which impacted on the cost-effectiveness of the clinic.</p>	<p><i>"We have to look at how we streamline our costs slightly or maximise the patients coming through to make it a cost effective service because it is not cost effective at the moment"</i> (FG02T1)</p> <p><i>"We're not getting enough patients through, that's why it's not cost effective ...if we've got two receptionists, a doctor and then One You counsellor that's a lot of people sat there and especially if You One aren't being used, then that's definitely not cost effective for them to be sat there all day and not to see any patients... We need to get the right balance of the right amount of patients through but also the right clinicians available. We need to balance that out. I don't think it's more expensive than they anticipated I think it's just the footfall needs to increase"</i> (KI02T1)</p>
<p>The number of service users attending the walk-in clinic was unpredictable, which made balancing staff costs difficult.</p>	<p><i>"Because it's a walk in clinic we don't know if we're going to get five people in or thirty so we could go ahead and get a second GP and only have five people in that day and the next week we say no don't worry and then we've got thirty. So it's just trying to sort of juggle the costs that way I think"</i> (KI02T1)</p>
<p>Costs were expected to reduce over time as a result of reduced appointment times once the research had ended and the use of technology at scale.</p>	<p><i>"Obviously it's a research project so you do have to spend...five to ten minutes explaining the whole evaluation side, the consent forms that side of stuff and just explaining the whole set up in the first place and then on top of that we are having to explain the whole care plan set up and which is another five or ten minutes so probably ... if you were aiming for twenty minute appointments for severely depressed people that wouldn't be unrealistic for core GMS primary care work actually"</i> (FG02T1)</p> <p><i>"So if the technology was spread over a wider population, it would be cheaper because the cost per patient would be less. Because a lot of it are just set fixed costs. So the more patients you have in it and the wider geography, means that the cost would really, really ease out. I think the starting's quite expensive but, as time goes on, the management costs will drop off"</i> (WS01)</p>
<p>The use of the technology was seen as expensive.</p>	<p><i>"It is still quite expensive to run and part of the reason it's expensive to run is because the technology is so expensive"</i> (WS01)</p>
<p>In the longer term, the benefits of seeing people with mental health needs early and by the right clinicians, was expected to result in reduced treatment costs.</p>	<p><i>"Somebody who's suffering with low level anxiety and depression is on a waiting list to talk to somebody but has got to wait 8 to 10 to 12 weeks to speak to somebody in which time their condition worsens, and they end up on medication. So I think there absolutely are cost savings and benefits with this model"</i> (WS04-05)</p> <p><i>"In terms of long term cost effectiveness, I could see that it would have quite a big impact... getting signposted to the correct service to begin with... short term, probably not"</i> (WS06-07)</p>

4.7. What could be improved, replicated and sustained?

Evaluation findings were further organised in Table 23 to extract (1) what improvements were needed to optimise the pathway, (2) which key elements then required sustaining long-term to ensure future success of the clinic, and (3) which key elements were key to replicate if a similar clinic was established elsewhere.

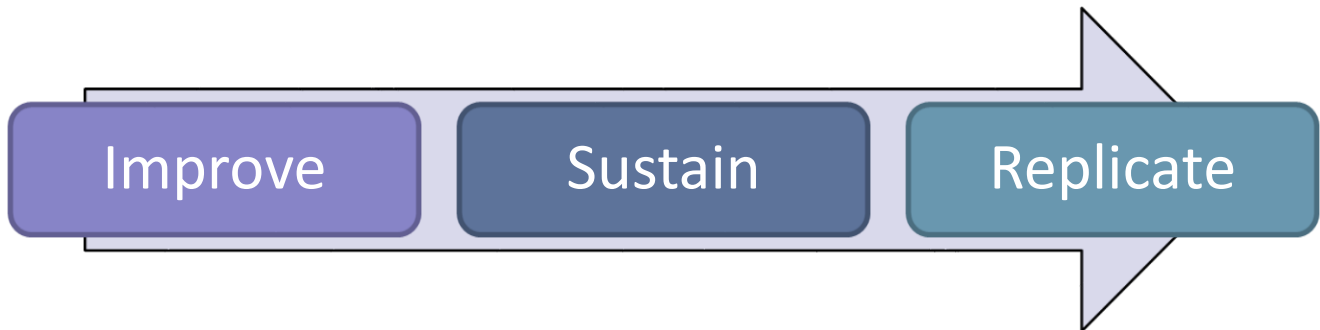


Table 23: Summary of elements that could be improved, sustained and replicated

IMPROVE	
Element	Supporting information/quotes
1. Widening referral and advertising to increase clinic use	<p><i>"It would have been a lot busier if they had signposted patients in, so there's probably one or two GPs have done that and the rest have not engaged at all" (KI01T1)</i></p> <p><i>"It pulls people in who are possibly at the more severe end and if it was renamed 'wellbeing', 'health wellbeing service' [it]would bring in a broader spectrum of patients rather than the severe end (FG01T1)</i></p>
2. Implementation into standard practice through integrated administrative support	<i>"You kind of need to get that integration between some of our more admin functions in the background... I think because the clinic's being run as like an isolated clinic, ... we haven't quite embedded it enough from an admin point of view" (KI03T2)</i>
3. Reduction of waiting times, especially with service users experiencing anxiety.	<p>Just over half of intervention group participants (54.4%, n=25) strongly agreed or agreed that they did not have to wait long to see a doctor in the service experience questionnaire conducted at the six month time point.</p> <p><i>"I was not that impressed because I was... I'd cued up behind one person and got to the desk. When I was called the doctors had been the second person, the computer hadn't even been loaded up so then the third person went ahead of me. I was... somebody who suffered from anxiety so that, for me, was a big thing." (SU06)</i></p>
4. Peer support provision to complement services	<i>"I'm wondering whether or not a peer support group might be beneficial, ... so kind of having that element of being able to go and meet with other people who are also experiencing those kind of difficulties just, you know, just might be an additional tool to have within the quiver." (SU46 at six-month follow-up)</i>
5. Alternative methods of triage outside of the i-spero technology to increase accessibility of care	<i>"I did the app out of obligation, because I was asked to by the clinic. I didn't find it helpful in the sense of my journey. I mean I could tell I was anxious I didn't need the app to tell me that, to be honest. I did it as part of, you know, participating in the study. But, yeah, it got too onerous after a few weeks" (SU23)</i>
6. Options to improve cost and sustainability include: Embedding the service into standard GP	<i>"The only way we continue to make it sustainable...if there's no additional funding, is we tweaked the pathway so that they just come into our normal service model" (WS04-05)</i>

	practice weekly hours, consider ways to access additional integrated services (IAPT and OneYou) to remove the need to fund these within the primary care service, co-location of services. These may offset the higher costs of running a separate Saturday clinic.	
7.	Further aligning the service model around needs for severe depression - assessing essential options for relevant treatment of this population	<p><i>"And they also got me to have some...got me into having some counseling quite quickly, which also is very helpful" (SU38)</i></p> <p><i>"I mean there would be weeks when I'd sit there and not have anyone in the end, which was right probably because they [the patients] were too severe. I'd get a couple, don't get me wrong, some people with weight issues and then they was signposted correctly but I didn't think it really warranted me sitting there all morning for that really it was a bit of a waste of resources and probably money if I'm honest" (K107T1)</i></p> <p><i>"when people are coming in they're not necessarily ready for our service so the people that are actually coming in are probably more... moderate to severe because [...] they're wanting the meds and they might then be with the GP for forty-five minutes [...] and then they're told oh well we're going to send you through to the One You service and then they're saying I want to go. I don't want to be here all morning. I want to go. But I think anecdotal feedback that we've had from the advisor that works here is that a lot of the people aren't actually ready for a behavior change intervention, which is essentially what we are about" (FG01T1)</i></p>
8.	Increasing referral rates from other GP practices in the area	<i>"There is history between the two practices, because they're run on different financial basis, there's a lot of... it is a very very awkward relationship... one or two people have come, I think, from [another medical practice] but whether they're self-referrals or whether they've been referred by the GP, I don't know" (WS02)</i>
SUSTAIN		
	Element	Supporting information/quotes
1.	A structured clinic based on triage and integration of services, i-spero and service user involvement	<i>"[T]he setting that you know it's a dedicated clinic for those sort of issues is really reassuring..." (SU54)</i>
2.	Providing options and choice in one place or dedicated clinic to support improvement in service user experience of care	<i>"I was under the assumption that I was just going to see a GP that day and then maybe see a counselor another day and then health and wellbeing, I wasn't, I didn't realise I was going to see all three in one hit, which was really good ..." (SU62)</i>
3.	Champions and effective leadership to support ongoing intervention success	<p><i>"The GPs have been really engaged. From a management perspective people haven't been up and running with everything from the outset so we've had to kind of be brilliant at slowly drip feeding the next thing that needs to happen" (FG02T1)</i></p> <p><i>"It would be very interesting to see in terms of trying to roll this out say beyond very supportive practices, would we have the same experience? So</i></p>

		<i>having those champions within the GP setting I think is critical for it to be able to work” (WS01)</i>
4.	Team reflection and communication with a flexible approach to adapt to service user need	<i>“[W]e’ve worked really well together and I think having that feedback from us all, we’re quite open and honest with each other, even if we disagree. We disagree and discuss and I think that’s brilliant and healthy” (FG02T1)</i>
5.	Timely access to treatment, avoiding waiting lists	<i>“I was able to just go when I felt I needed to as opposed to if you feel you need to and then the appointment sometime away whether that’s an hour away or a day away or a week away it’s not necessarily getting to you when you need it. I think that was important” (SU20)</i>
6.	Retaining multi-disciplinary skill-mix	<i>“Well from one room to another between the three different disciplines if that’s the right word [...] So I felt that I was getting someone’s complete attention who understood the nuances of my condition and had the time to think about it if you know what I mean. I think that worked” (SU20)</i>
REPLICATE		
	Element	Supporting information/quotes
1.	Professionals based in primary care with a special interest in mental health and advanced skills as a result	<i>“We’ve got lots of clinicians, patients generally see a different clinician every time and quite often generally mental health isn’t the interest of many clinicians ... myself and [name] have got a lot of interest in it so you get more empathy” (K108T2)</i>
2.	Taking time with service users to provide holistic care	<i>“It’s amazing that you can just turn up and get to see really skilled doctor who is willing to give you the time to talk through things” (SU03 at six-month follow-up)</i>
3.	IT support would be required both from practices to support services users in use of the i-spero tool but also from the i-spero team to support practice implementation	<i>“I really do like the technology, I find it really helpful to use alongside speaking to people, I think generally people feel, I think they really like it, I think they like monitoring themselves as well, it’s a positive thing” (K101T1)</i> <i>“We provided a live help desk availability ... so I think that really helped provide confidence for everybody in terms of making sure that the software did work... because of that live support that was provided right at the beginning...” (WS10)</i>
4.	Symptom tracking was seen as key to service user improvement	<i>“I think it was really useful having that element of being able to self-monitor by using the PHQ-9 and GAD-7 and kind of having it in a place where you could see progress or deterioration, dependent on week-by-week basis. But also the fact that it was quite reassuring, reaffirming or [...] identifying that you might need to go to the clinic to look at a change to treatment. So I think it was really user-friendly and it was a really good therapeutic tool in itself, even though it was kind of mostly a monitoring one” (SU46 at six-month follow-up)</i>

5. Discussion

The new service was effective in its primary aim of improving mental health support for those experiencing low mood, anxiety and depression in a GP practice setting. This was evidenced in those receiving the intervention by a reduction in depression symptoms (symptoms of depression, anxiety and suicidal ideation) and improvement in service user sense of wellness. The reduction in depressive symptoms and suicidal ideation was reflected when comparisons were made with standard care, however, differences between groups were not observed for anxiety symptoms or a sense of wellness. A particular strength of this study is the 'real world' observation and assessment of service user outcomes and implementation¹⁰⁻¹¹. The difficulties involved with implementing a new multi-disciplinary care model with combined digital technology were complex. Therefore, allowing for rapid feedback from the evaluation, flexibility and a dynamic intervention that could be updated to ensure it was fit for purpose and responsive to service users was critical.

The positive effects of the use of digital applications for the management and care of those with common mental health disorders are well documented^{12, 40}. The technology used to support the multi-disciplinary clinic, i-spero, was reported as easy to use and beneficial because it enabled service users to record and track their progress over time. Practitioners also found i-spero particularly useful in guiding triage and clinical management; however, it may not be suitable for everyone, due to the nature of their condition, age, digital skills or other factors. Access to alternative forms of symptom assessment (such as paper copies, free to access online surveys using tablets or practitioner-led symptom assessment) would improve accessibility for those unwilling or unable to use the technology and increase service user choice. Key features critical to the technology as observed by service users and practitioners included ease of use, the ability to rate mood/anxiety levels on a scale and the option to personalise the app in particular for practitioners recording care plans (which has been reflected in other studies⁴¹). Elements identified as required for service user engagement of i-spero and in other studies⁴² include: understanding the purpose of the assessments (in particular the PReDicT test), the practitioner's role in reinforcing and supporting app use (although this added to workload) and reduction in burden of the system created by service user deterioration or suicide alerts. Many individual studies have shown improvement in common mental health disorder symptoms with digital technology use. However, critical to the success of any digital technology for symptom monitoring and care is engagement and regular use which has been shown to be linked with symptom improvement in many cases⁴²⁻⁴⁶.

Service user improvement was due to the holistic approach with 'joined up' and co-ordinated care from multiple service providers. Holistic care was enabled by the integration of the clinic with other supporting therapy services, the technology and service user involvement. The service also served to meet the needs of the local population and potentially the rise in mental health need as a result of COVID-19. The care model critically led to better integration and co-ordination between primary care, other NHS services from other providers and other social and voluntary care sector services. Embedding these additional services in primary care may have enabled improved access and willingness to engage in these types of therapy. Critically, to enable scale and spread, an integrated service should be designed within emerging integrated structures such as primary care networks and the quality of relationships across services will plan an important role in delivery at scale.

There was a high level of service user satisfaction, due to the quality of care received from individual practitioners and the timely single point of access to assessment and multiple services, specific to their needs (i.e. better patient-centred care). A key factor in the success of the clinic was the multidisciplinary team approach involving practitioners who had a special interest and skills in mental health and wellbeing. Therefore, increasing and embedding GPs with special interest roles or other mental health specialists within primary care may support care for common mental health disorders⁴⁷. Practitioners also believed the service enabled users to recover more quickly as service users were able to monitor their progress and take part in shared decision-making (self-management). Of significance here was the regular use of service user-reported outcome measurements (PROMs), in this case PHQ-9 and GAD7, to inform clinical management and treatment. Indeed, regular use of PROMS alone may be sufficient to increase quality of care for depression in a primary care and community setting^{6-7,9}.

There is a higher level of depression in the locality than the national average (16.5% within the locality compared to 11.6% nationally), signifying that the service had identified and was responding to a local need or gap in service provision. Service users, overall, had more severe symptoms of depression and anxiety than anticipated when designing the new service pathway. This was felt to be due to a lack of capacity of mental health services locally, mirroring the national picture⁴⁸. The severity of presentation symptoms for depression and anxiety led to the need to change and adapt the pathway to meet the needs of the population. As in many new service initiatives, having champions and effective leadership was instrumental to success⁴⁹. An over-reliance on a small number of key individuals makes the service vulnerable to staff change.

The higher costs of the intervention are reflective of an enhanced service, running outside of usual clinic hours by multiple agencies. The nature of the clinic as a 'walk-in' service also makes it difficult to accurately anticipate demand and, therefore, staffing (with associated costs). It is likely that costs could be reduced by integrating the clinic, service user follow up and administrative support within usual weekday provision and/or increasing the number of service users⁴⁹. Embedding the service into standard GP practice hours would also improve sustainability of staffing in the longer term. Consideration of ways to access additional integrated services (IAPT and OneYou) within their usual business hours would remove the need to fund these additional IAPT and OneYou services within the primary care service, for example, co-location of services. The cost of the technology might be reduced by its use across a wider geographical footprint (more Primary Care Networks). It is hypothesised that cost benefits might occur in the longer term by reducing the need for secondary mental health care and improving the prevention of suicide through proactive service user symptom monitoring and the i-spero suicidality alert system.

COVID-19 was a significant contextual factor influencing both the mode of service delivery and the number of service users being referred to the service. Despite recruitment to the evaluation having been completed before COVID-19 lockdown, the situation may have affected symptom reporting of those still in the follow up period reducing the changes in symptoms detected.

Going forward, there is a need to continue to seek innovative ways to increase referral/self-referral rates and reduce waiting times, perhaps by using a mixture of booked vs 'walk-in' appointments. Opportunities for peer

support between service users was also suggested as a way to enhance the service further. Most importantly, committed funding to support and sustain enhanced mental health care within a community setting is essential.

6. Limitations

Limitations to this evaluation included a lack of ethnic diversity in the sample groups as reflected by the local population characteristics. A lack of quantitative patient-reported outcome measures being collected within standard care practice left limited options for comparative data collection and analysis with the intervention. Recruitment fell short of optimum sample size for the standard care group. Furthermore, the combination of novel technology and a newly designed service limited the ability to attribute changes in service user outcomes in particular to these separate elements of the intervention. As the evaluation was conducted at a single GP practice this created limited practitioner involvement in the delivery of the intervention and care provision which may have decreased the variation in outcomes and experiences in continuity of care compared to a study involving more delivery sites. Although the study evidenced improvement in service user outcomes, the variability of service provision across primary care means that transfer of the intervention as designed to other localities is unlikely, however, replicable elements were identified that could be taken up by other primary and community services. Finally, the context of COVID-19, although not impacting on evaluation recruitment, may have affected changes in participant symptoms during the follow up phase.

7. Conclusion

The new service was effective in improving mental health support for those experiencing low mood, anxiety and depression in a GP practice setting as evidenced by a reduction in depression symptoms compared to standard care, and the personal perceptions of benefits as highlighted by participants. The technology used to support the multi-disciplinary clinic, i-spero, was easy to use and beneficial, enabling service users to record and track their progress over time; a feature that also enabled practitioners to guide triage, treatment and clinical management. Service user improvement was due to the holistic approach with 'joined up' and co-ordinated care from multiple specialist service providers in a timely single point of access. The intervention was more costly than standard care, however, this was reflective of the enhanced service, running outside of usual clinic hours by multiple agencies. Costs could be reduced by integrating the clinic, service user follow up and administrative support into normal business hours (weekday provision) and/or increasing the number of service users or geographical footprint. It is hypothesised that cost benefits might occur in the longer term through reduction in need for secondary mental health care and improving the prevention of suicide.

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9. References

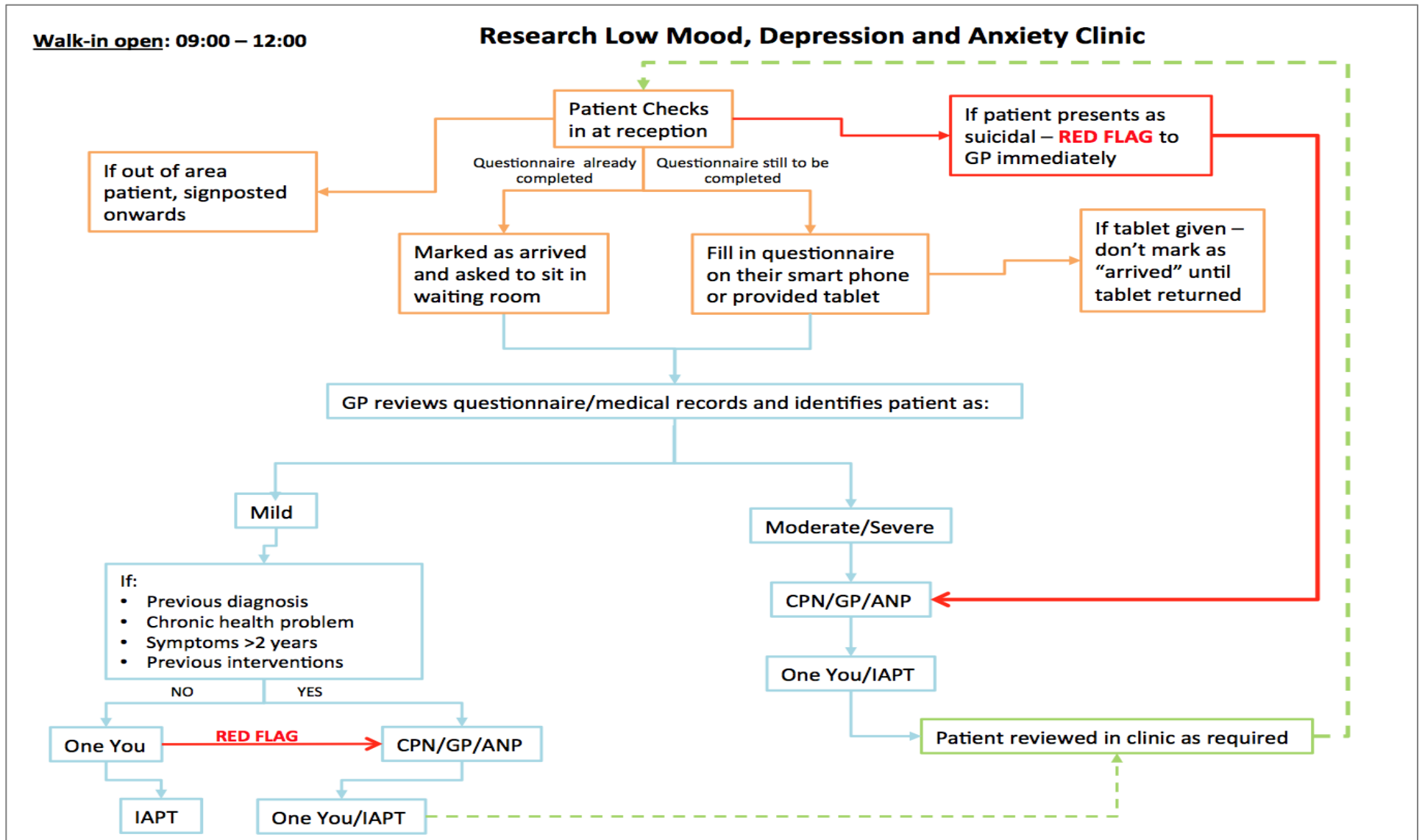
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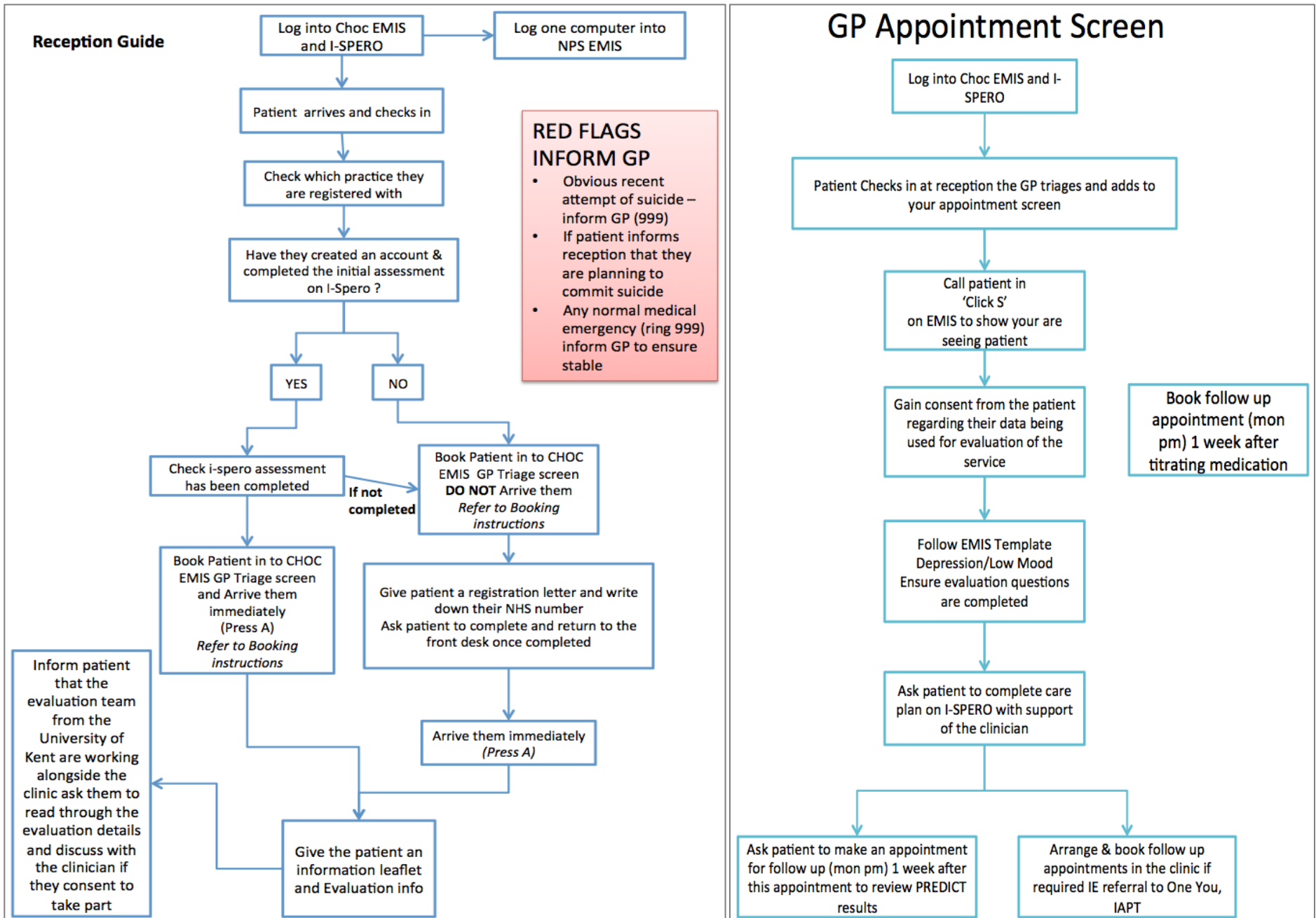
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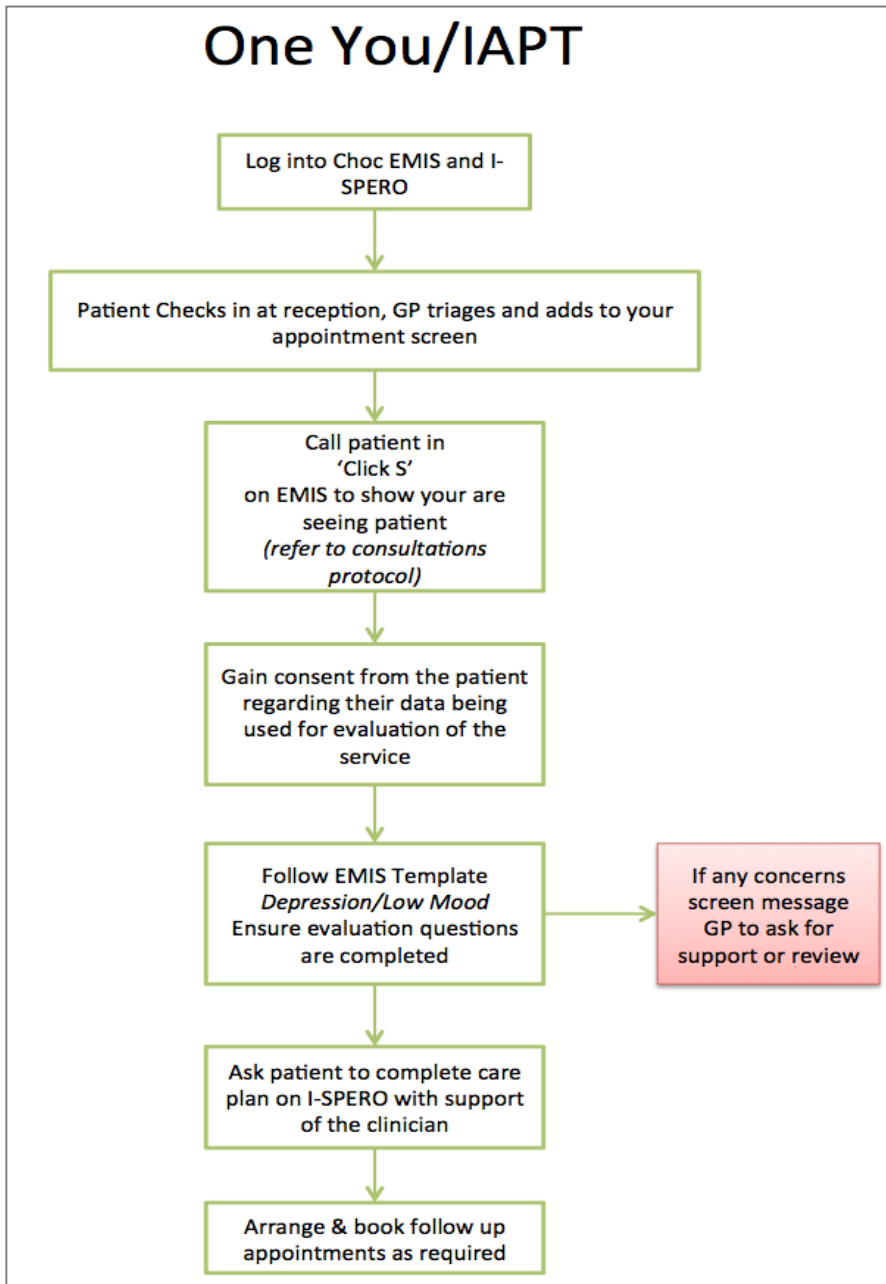
10. Appendices

Appendix 1: Intervention pathway flow charts – originally designed pathway prior to start of service

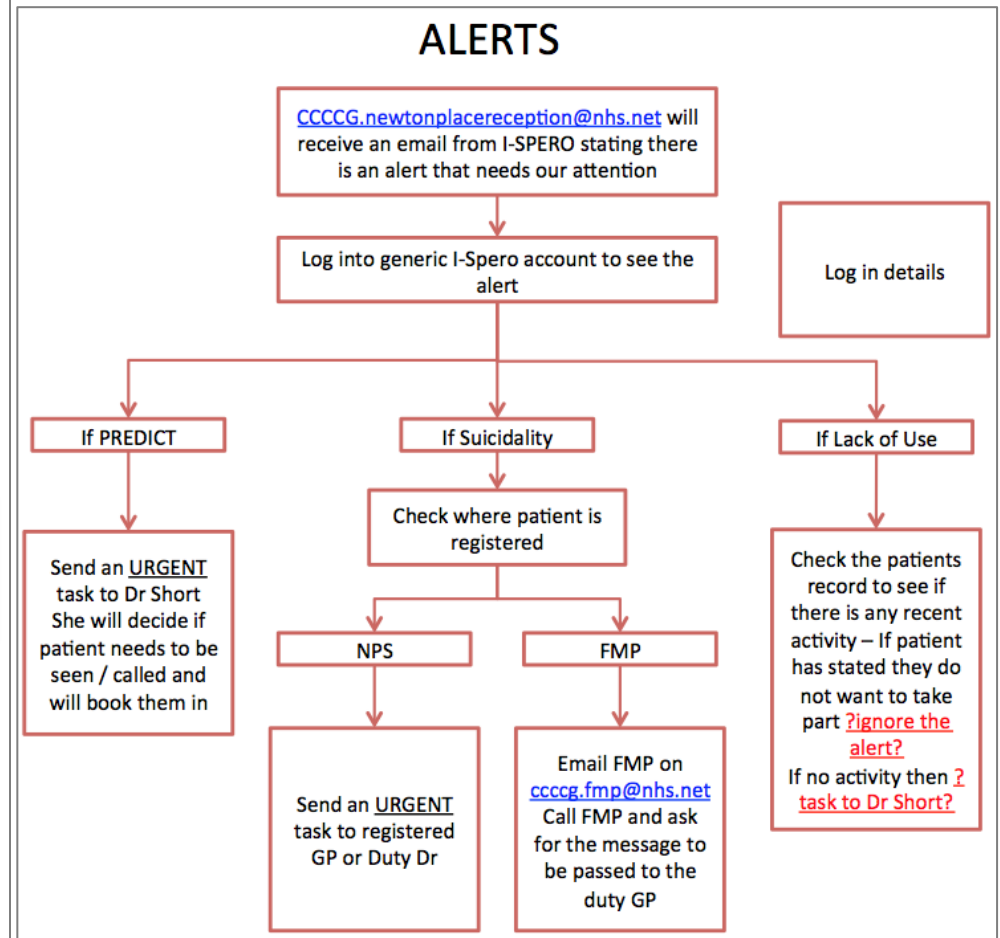




One You/IAPT



ALERTS



Appendix 2: Key changes to the intervention during implementation

Table 5 below details changes made to the intervention over the duration of the evaluation recruitment and follow up period (6th July 2019 to 30th June 2020).

Changes to clinical pathway		
Change made	Reason	Date of change
Wi-Fi boosters purchased for the clinic	Connectivity-related drop-outs and log-outs were reported by service users and staff; in case of poor Wi-Fi, the PReDICT test was reported to 'loop'	September 2019
Clinic rebranded as more of a 'wellness' clinic and not simply for depression	Rebranded in order to try to encourage low mood and mild depression service users to attend	September 2019
A new leaflet that better-explaining the different parts of the clinic provided, including summary information of One You and IAPT service users available outside the clinic	Designed because service users reported lack of clarity on what to expect from different part of the clinic before the appointments. Clinic staff also reported not knowing the full remit of IAPT and One You services	November 2019
Additional support provided at the end of consultations by practice receptionists for i-spero use	To increase use of care plan functionality, receptionist supported service users to input care plans at the end of the consultations at the clinic	November 2019
Some clinic follow-ups carried out by the GP during the week.	Rising numbers of walk-ins and repeat follow-ups resulted in level of demand hard to address within clinic time.	November 2019
Change in the order of healthcare professional seeing service users. Wellness support moved to first appointment to be conducted which triage happening	In order to reduce waiting times and increase use of wellness services	November 2019
Order of services returned to at start of intervention. Returned to triage and GP consultation first	Wellness services were not appropriately skilled to see severe service users without first consultation with GP after triage.	January 2020
Second GP working at the clinic added	To reduce waiting times and cover increased follow up appointments a second GP was recruited to work within the clinic team	January 2020
Nurse practitioner working at the clinic	To reduce waiting times and added pressures resulting from COVID-19	March 2020
COVID-19 adaptation to online consultation only	COVID-19 resulted in service users being asked not to attend in person to reduce risk of COVID-19 transmission	March 2020
Changes to i-spero technology		
Change made	Reason	Date of change
Software changes on recommendations by the Patient and public involvement group.	Multiple functionality changes to ensure usability	June 2019

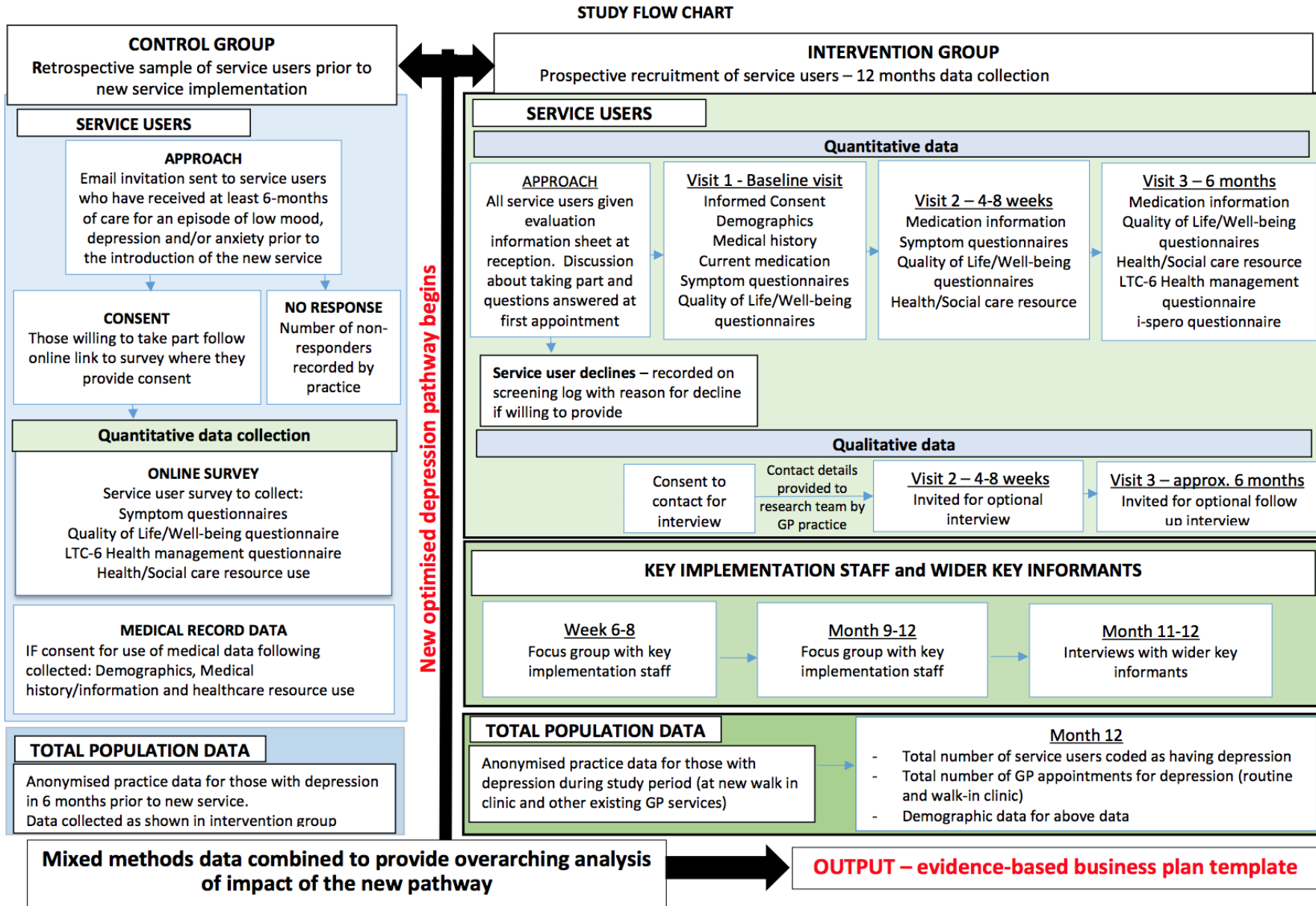
Software release 1.1	Production launch of i-spero for the Kent CCG	July 2019
Software release 1.2	Multiple features and change requests including: <ul style="list-style-type: none"> • Fix for bug where patients missing off the “All GP Practices” but appearing on “GP Practice 1”. • OPT-D Participant ID field added • GP Practice Dashboard Patient List view - Search by full last Name feature (e.g. Smith not Smi). • Personal details - DOB Age range 18-70 has been changed to 18+. • Results tab Graph on Dashboard - Hover over link on plot point is larger so more usable. 	September 2019
Software release 1.3	OPT-D Study Dataset reports added	August 2019
Changes to alerts – overly risk averse alerts	Alert parameters for symptom deterioration amended so that they are only triggered for moderate or severe service users to reduce GP practice burden	Sept 2019
Access to i-spero for wider practice GP team	Enable named GPs not involved in the clinic to view i-spero assessment and provide continuity of care for service users returning to normal hours appointments	Sept/Oct 2019
Software release 1.4	Enabling Care Plans to be added/editable by GPs (highest priority issue identified by Kent CCG) without requiring the patient to log on themselves. Log-in issues resulted in much longer consultation times, resulting in fewer service users being seen during the clinic.	November 2019
i-spero central tech support ceased	Discussion between lead practice and P1vital Ltd resulted in agreement to remove central tech support provided by P1vital Ltd	Feb 2020
i-spero central tech support reinstated	Need for additional central tech support as users were experiencing difficulties accessing the technology and COVID left users unable to visit the surgery for support	March 2020

There were other aspects that clinic staff commented on as needing improvement, but ones that were either outside of their control or could not be addressed during the evaluation period.

There were:

- Information sharing issues, which meant that triage notes would not always appear on the EMIS system in time for clinic staff to see the notes from the previous clinician whom the service user saw on the day
- Some staff reporting a small number of service users coming back each week for a number of consecutive weeks and were not sure how to address this
- Record keeping was reported to take up an unexpected amount of time, affecting time that could be spent seeing service users

Appendix 3: Evaluation design flow chart



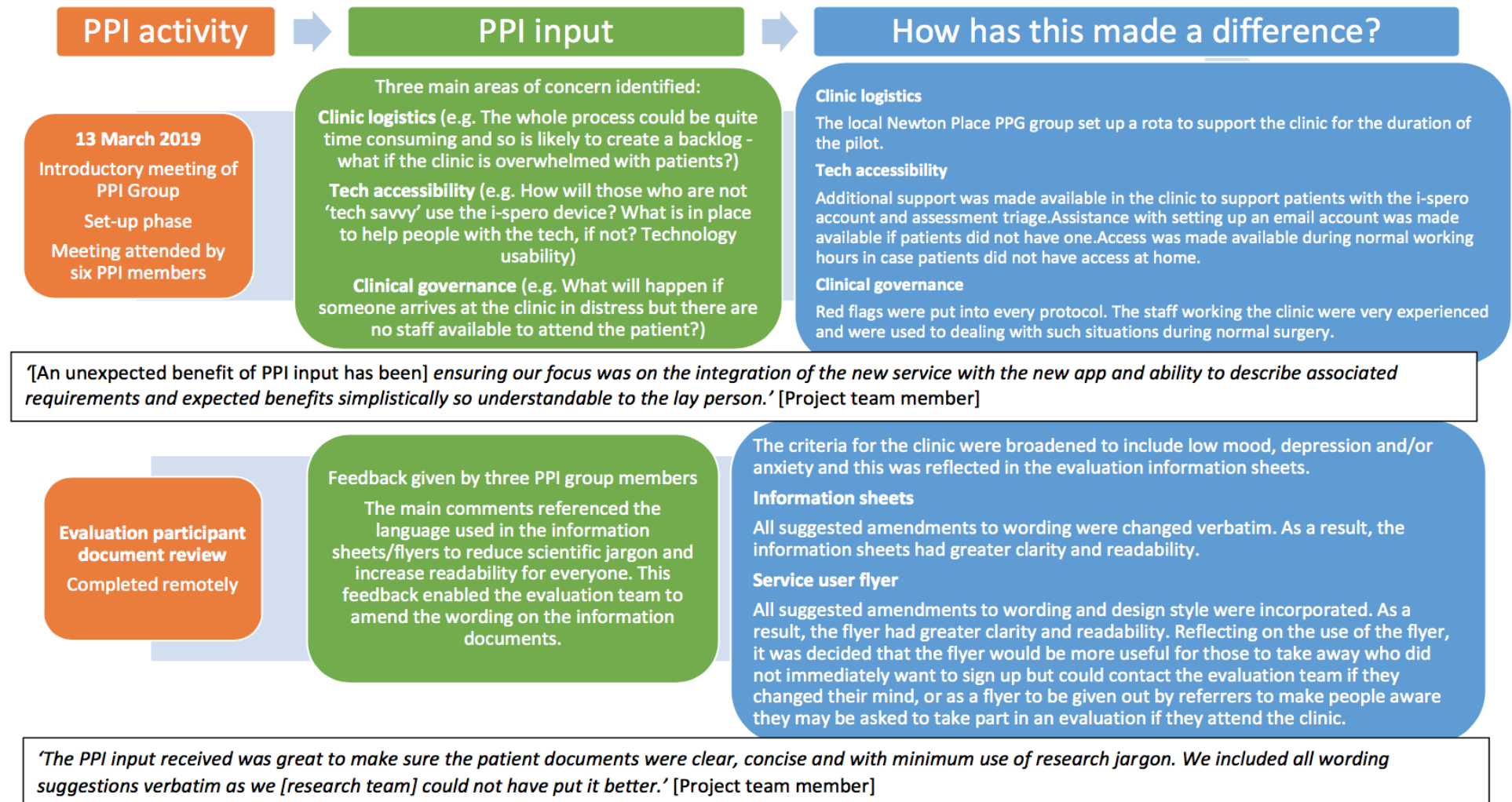
New optimised depression pathway begins

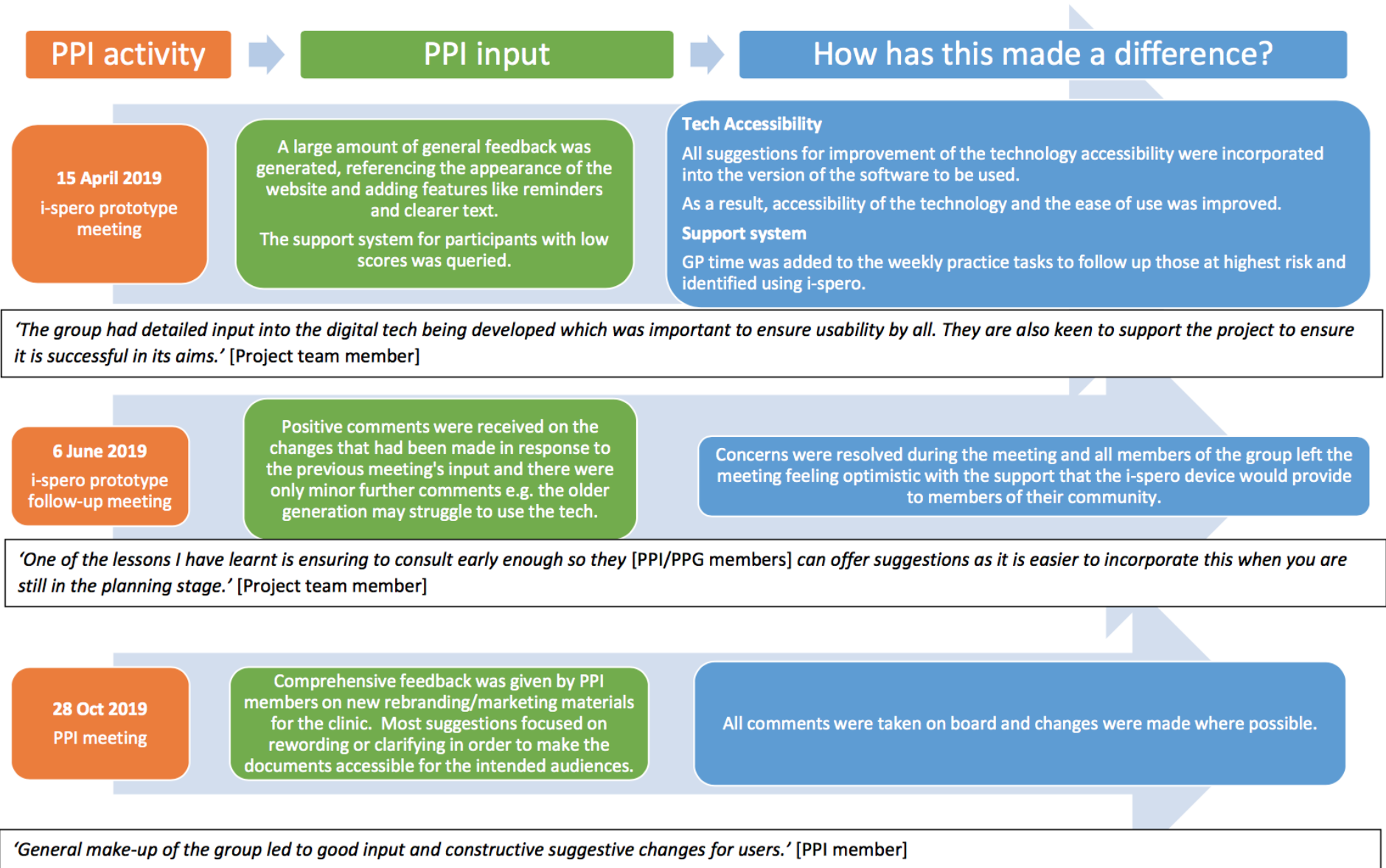
Appendix 4: Public Involvement overview and impact

How has Patient and Public Involvement (PPI) made a difference?

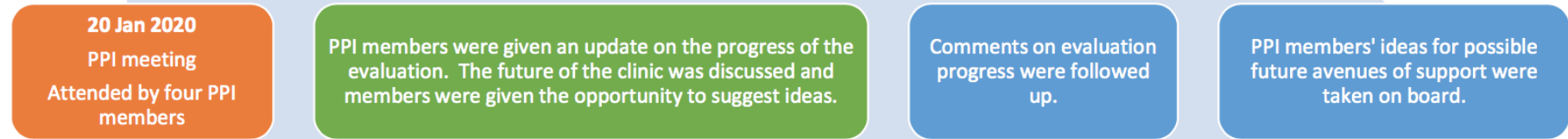
The PPI group comprised of people invited from the following sources:

- Faversham town GP practice Patient Participation Groups (PPGs)
- 'Opening Doors to Research' patient and public involvement group, Centre for Health Services Studies, University of Kent
- Maidstone and Mid Kent Mind – Wellbeing cafés in Ashford and Maidstone

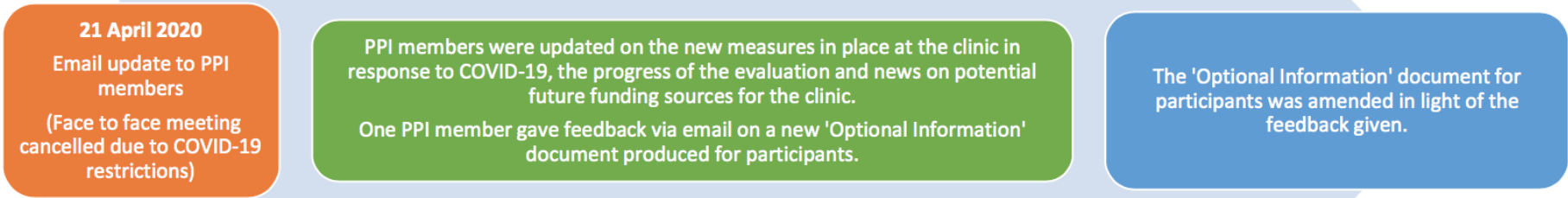




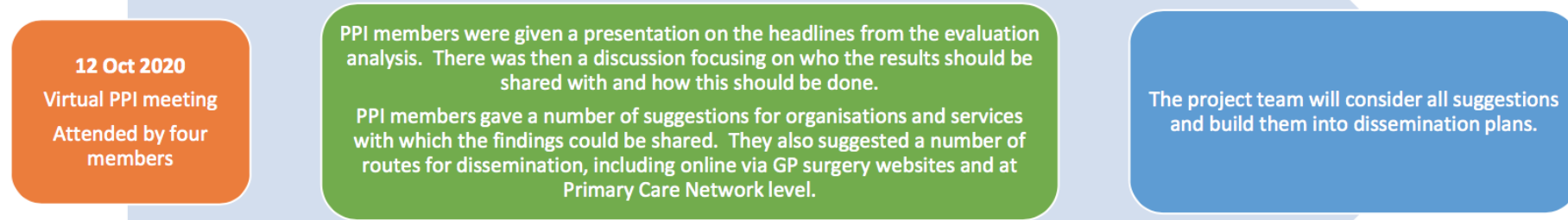
PPI activity → **PPI input** → **How has this made a difference?**



'PPI is often overlooked or done as a tick box exercise. In this project, we have had a plan from the outset and it [PPI input] has added value and identified issues or made recommendations that would not have been considered otherwise.' [Project team member]



'It is important to include feedback from PPI, as often when you are involved closely with a project it can be easy to just consider the logistics of the project but can be difficult to consider alternative perspectives... from the patient's point of view.' [Project team member]



'It has been both interesting and a pleasure meeting the other members.' [PPI member]

Appendix 5: Unit costs used in the health economic analysis

Appendix 5.1: Unit costs of running the Saturday clinics

Item	Unit cost (£)	Duration	Source
Reception	20.74 per hour	9 hours per week ^a	Newton Place Surgery
Management	28.35 per hour	4 hours per week ^{a,b}	Newton Place Surgery
GP1	439.95 per session	1 session per week ^{a,c}	Newton Place Surgery
GP2	109.98 per hour	2 hours per week ^{a,b}	Newton Place Surgery
Nurse	34.37 per hour	4 hours per week ^{a,b}	Newton Place Surgery
IAPT	130 per week	n/a	Newton Place Surgery
OneYou	446.75 per month	n/a	Newton Place Surgery
<i>Additional (monthly) costs associated with</i>			
Reception (overtime)	20.74 per hour	10 hours per month ^a	Newton Place Surgery
Management	40.10 per hour	24 hours per month	Newton Place Surgery
Management admin	18.90 per hour	40 hours per month	Newton Place Surgery
GP sessions	439.95 per session	4 sessions per month ^c	Newton Place Surgery

n/a, not applicable. ^aon average ^bManagement, GP2 and nurse were not present in all Saturdays. ^cEach session is equivalent to 4.25 hours per week.

Appendix 5.2: Service user-reported health and social care use and associated unit costs

Item	Unit cost (£) ^a	Source
<i>GP services</i>		
GP	39	Personal Social Services Research Unit (2019), pp. 120, per surgery consultation lasting 9.22 minutes (including direct care staff costs and qualifications) ^b
Nurse practitioner	42	Personal Social Services Research Unit (2019), pp. 118, per hour (including qualifications)
Mental health worker/nurse	55	Personal Social Services Research Unit (2019), pp. 117, Band 7, per hour
OneYou	39 ^c	North and West Kent OneYou, per appointment
<i>Community-based services</i>		
Community mental health centre	55	Personal Social Services Research Unit (2019), pp. 117, Band 7, per hour
Group therapy or talking therapy	55	Personal Social Services Research Unit (2019), pp. 153, Counsellor Band 7, per hour
Dietitian	56	Personal Social Services Research Unit (2019), pp. 143, Band 7, per hour
<i>Social care services</i>		
Occupational therapist	48	Personal Social Services Research Unit (2019), pp. 133, per hour (including training costs)
Service user support or self-help groups	25	Personal Social Services Research Unit (2019), pp. 136, per hour
<i>Hospital services</i>		
Acute psychiatric ward	226	National Schedule of Reference Costs 2018-19, Mental health, Code: MHST, per care contact
Psychiatric emergency/intensive care/crisis centre	217	National Schedule of Reference Costs 2018-19, Mental health, Code: MHST, per care contact
Psychiatrist	46	National Schedule of Reference Costs 2018-19, Total outpatient attendance, Code: 722, per appointment

Occupational therapist	70	National Schedule of Reference Costs 2018-19, Total outpatient attendance, Code: 651, per appointment
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^aAll unit costs, except where specified, were adjusted to 2020 prices using the CCEMG-EPPI Centre Cost Converter (<https://epi.ioe.ac.uk/costconversion/default.aspx>).

^bNo separate unit cost was provided for telephone consultations *per se*.

^cProvided in 2020 prices.

Appendix 5.3: Medication use and associated unit costs

Item	Dose	Unit cost (£) ^a	Source
Citalopram	5mg	0.22	eMIT 2019, code: n/a, package of 28
Citalopram	10mg	0.26	eMIT 2019, code: DDC129, package of 28
Citalopram	20mg	0.31	eMIT 2019, code: DDC135, package of 28
Citalopram	30mg	0.50	eMIT 2019, code: n/a, package of 28
Citalopram	40mg	0.69	eMIT 2019, code: DDC130, package of 28
Duloxetine	30mg	1.61	eMIT 2019, code: DDC189, package of 28
Escitalopram	5mg	0.43	eMIT 2019, code: DDC158, package of 28
Escitalopram	10mg	0.59	eMIT 2019, code: DDC156, package of 28
Escitalopram	15mg	1.04	eMIT 2019, code: n/a, package of 28
Escitalopram	20mg	1.28	eMIT 2019, code: DDC157, package of 28
Fluoxetine	20mg	0.25	eMIT 2019, code: DDI014, package of 30
Fluoxetine	60mg	0.80	eMIT 2019, code: n/a, package of 30
Mirtazapine	15mg	0.46	eMIT 2019, code: DDC177, package of 28
Mirtazapine	30mg	0.64	eMIT 2019, code: DDC080, package of 28
Mirtazapine	45mg	0.77	eMIT 2019, code: DDC178, package of 28
Paroxetine	30mg	1.08	eMIT 2019, code: DDI013, package of 30
Pregabalin	150mg	2.69	eMIT 2019, code: DDH134, package of 56
Quetiapine	50mg	3.25	eMIT 2019, code: n/a, package of 60
Quetiapine	75mg	3.32	eMIT 2019, code: n/a, package of 60
Quetiapine	150mg	3.39	eMIT 2019, code: DDB181, package of 60
Sertraline	50mg	0.66	eMIT 2019, code: n/a, package of 28
Sertraline	100mg	0.79	eMIT 2019, code: DDC041, package of 28
Sertraline	150mg	0.95	eMIT 2019, code: n/a, package of 28
Sertraline	200mg	1.60	eMIT 2019, code: n/a, package of 28
Venlafaxine	37.5mg	0.90	eMIT 2019, code: DDI015, package of 56
Venlafaxine	75mg	1.79	eMIT 2019, code: DDI016, package of 56
Venlafaxine	150mg	1.80	eMIT 2019, code: DDC068, package of 28

n/a, not applicable. ^aAll unit costs were adjusted to 2020 prices using the CCEMG-EPPI Centre Cost Converter (<https://epi.ioe.ac.uk/costconversion/default.aspx>).

Appendix 6: Recommendations for improving i-spero and usefulness of features

Interviewees were asked to comment on the features they found most useful features of the app, as well on whether any changes or additional functionality was desired. Due to the fact that the way service users and staff interacted with i-spero, feedback below is separated into service user, staff and wider informant groups.

Service User recommendations	
The most common suggestion (by far) was being able to add comments next to GAD-7 and PHQ-9 scores to contextualise change in scores.	<p><i>"I still think it would be nice to just have a section on it where you can write notes. [W]hen you're monitoring it would be really useful to know actually that was because that happened this week or because I knew I had that coming up or, you know, what ever it is I just think that's quite helpful" (SU3 at six-month follow-up)</i></p> <p><i>"Put a reason in for...a specific...event or something that may have caused an up or down because at the time it wouldn't matter but if you were looking back it would give you a reason as to oh yeah I was bad that week but this is why. Because later on you probably wouldn't remember why without looking in there..." (SU05)</i></p>
One service user also suggested that inputting contextual information may help identify triggers for dips in mood	<p><i>"[T]here's no flexibility is there, it's just the questionnaires, there's no... You can't input a paragraph or explanation. It might be good for people with other, like eating disorders and things like that so there's a trigger, they might start recognising the triggers of why..." (SU66)</i></p>
Listing medication that is taken at different intervals than currently offered	<p><i>"I had another medication that I wanted to list on it and it basically a and it's like a migraine prevention injection that I have once a month but because of the type of medication there wasn't really an option for it so because I think it only had suggestions for like once daily or like twice daily but I only take it once a month [...] I ended up putting once daily and then wrote a note saying this is once a month or something" (SU01)</i></p>
Ability to change medication records easily	<p><i>"I've had change of medication and bits like that...it's not always been intuitive to me. I've got there but it's not been intuitive and...other than that I think it's pretty good actually" (SU20 at six-month follow-up)</i></p>
Shorter or more varied Predict test content	<p><i>"I think the face recognition one was really lengthy and I think when I first did it and I was kind of feeling really low that was the only one that just felt a little bit overwhelming" (SU03)</i></p> <p><i>"[T]he part that did drive me nuts was seeing all those faces again and again and again. Is it happy, is it sad, is it...this that and the other. That was quite infuriating, to be honest with you [...] I get the science behind it that you're making a snap judgment on reading emotions I do get that but it was...it was nicer to see maybe a few different faces or something" (SU06)</i></p>
Different assessments to PHQ-9 and GAD-7 (both in terms of the questions and in terms of response options)	<p><i>"I don't know if it can be tailored in any way to specific scenarios because I did feel that all though I was answering the questions I almost feel like I was lying because the way the question was worded wasn't sort of particularly relevant to my situation [...] I just think maybe carers, people who are full time carers fall into a slightly different category? I'm trying to do this this and this, you know, and I suppose in one way that's anxiety because I haven't got the time to do it and feeling overwhelmed all the time" (SU16)</i></p>

	<p><i>"[I]f there was more options in terms of responses, maybe that could prove more helpful to the individual and to the service" (SU44)</i></p>
<p>Different assessments to PHQ-9 and GAD-7 (both in terms of the questions and in terms of response options)</p>	<p><i>"I don't know if it can be tailored in any way to specific scenarios because I did feel that all though I was answering the questions I almost feel like I was lying because the way the question was worded wasn't sort of particularly relevant to my situation [...] I just think maybe carers, people who are full time carers fall into a slightly different category? I'm trying to do this this and this, you know, and I suppose in one way that's anxiety because I haven't got the time to do it and feeling overwhelmed all the time" (SU16)</i></p> <p><i>"[I]f there was more options in terms of responses, maybe that could prove more helpful to the individual and to the service" (SU44)</i></p>
<p>Clearer benchmarks for PHQ-9 and GAD-7 scores and ability to look up past scores on specific items</p>	<p><i>"And there's lots of data that you can see about yourself, obviously the time it takes to react and so forth but there's nothing to say whether that is within normal range. Whether that's below normal, you know, there's no kind of understanding of what that predict test is doing" (SU04)</i></p> <p><i>"[T]here was no way to look back at previous answers, I don't know if this is a thing that was done on purpose or not but I found that I wouldn't remember whether I'd scored a certain thing a 6 or a 7 and in some ways you're kind of making your own boundaries for what a 6 is and what a 7 is or whatever it might be, so sometimes you think well, I am feeling better than last week but I don't remember whether I put 6 last week or a 7 and so I don't want to, you know, give the wrong information" (SU59)</i></p>
<p>More sensitive suicidality assessment questions, differentiating between suicidal feelings and suicidal intent</p>	<p><i>"[S]o there's a question which asks something along the lines of, you know, do you feel like it would be better if you weren't here, or if you were dead, or something like that, and my answer to that on a number of occasions triggered a phone call from the GP, which is fine, but I felt a bit guilty that you know, they were taking up their time, and I guess the only thing would be as sort of a differentiation between that question and sort of another one being 'do you have any intention to harm or kill yourself' [...] probably could save the doctors some time as well if it was made a bit more explicit" (SU33)</i></p> <p><i>"Sometimes it is very hard to judge how to answer that [...] especially that thing of things like have you thought you'd be better off dead or...you know, have you thought of suicidal...well when I was suicidal that was very clear cut. I don't know if that means...if I think I would rather not be alive now does that cover" (SU36)</i></p>
<p>An app instead of a website link</p>	<p><i>"There's just an online link so for me actually having an app on the phone that would be a better option" (SU06)</i></p> <p><i>"So, rather than being a desktop-based or web browser-based programme, to have something specific for iPhones and Android users that could then set up notifications that come through onto your front screen" (SU17 at 6-month follow-up)</i></p>
<p>Ability to choose the most convenient time to receive reminders</p>	<p><i>"It would be really good if you could choose what time of the day you got sent the reminder emails because they just come through at half eight in the morning but at that time I've already been at work for three quarters of an hour so if I've forgotten</i></p>

	<i>to take my tablets it's too late. So I would like to be able to choose what time I get that email through in the morning because it's very useful to have the reminder...but, yeah like I say it would be good if you could choose what time you got it" (SU04)</i>
Ability to set and track personal goals on the app	<p><i>"[I]t would be really interesting to...again they can show it like a graph like on the depression and anxiety and day-to-day tasks if they could show some kind of a graph or something like that that interprets all those results a little bit more it would be good to see as well" (SU04)</i></p> <p><i>"[S]ome sort of habit tracker where you can put various different tasks that you want to do during the day being able to tick them off" (SU17)</i></p> <p><i>"[W]e say fitness helps us, we say it's good for the mind, if we was tracking that and tracking our minds at the same time maybe we would see a crossover and then maybe it might click into people's heads "do you know what, you felt better last week - but that's because you went out every day and you ran the school field or that's because you didn't start eating all that crap out of the cupboard" (SU46)</i></p>
Information on how to access other services	<i>"Perhaps links to the other services [...] Like the counseling service and the community service, have links to what they do as well within the application. And it kind of...if you look at it as a hub for treatment of which medication and targets and reducing alcohol of that's a problem or whatever all parts of that as well as your weekly reviews, you know, having used additional support from there, it might be useful for some" (SU20)</i>
Ability to seek professional advice via the app	<i>"I suppose the only thing you could ask is maybe to submit some questions that could be put to practitioners that use the service about advice and what their thoughts are on it. So I've had some sort of general questions of whether I should switch the time of day I take my medication and stuff like that so yes if you could pose a question that could be picked up by one of the GPs or therapists and their advice, might be useful" (SU54)</i>
Ability to share app assessment scores with other providers (e.g. counselling)	<i>"[E]very time I went to see [the counselor] there were almost identical sheets that you had to fill out at the start of every time [...] I've got no problem if that information was passed around" (SU44)</i>
Signposting/information on arranging repeat prescriptions	<i>"I think it would be great on there if you could generate something through the portal that says, I need to re-order my next repeat prescription instead of me walking down to Boots" (SU70)</i>
Generating alerts not only when scores drop, but also when they stay the same (i.e. someone remains clinically depressed based on the scores without a deterioration)	<i>"I suspect just to come up with the if your flat on medication and your scores haven't come down it's probably a good idea to go to the clinic or whatever. It seems to only prompt that when there's been a change in medication" (SU20)</i>
Text alert or push-notification option	<p><i>"I know it sends you emails but text alerts would also be quite useful" (SU11)</i></p> <p><i>"[T]here should be some sort of an alarm or something sort of like that goes "come on, you've not done this today" (SU65)</i></p>

<p>Issues with log-in were also reported by a group of service users:</p>	<p><i>"[O]n my tablet that I use it occasionally, I try to log in, it tries to sign me in as a new user rather than logging me in as the user I am but if I refresh it logs me in properly if that makes sense. So I've have that glitch a few times but other than that no other glitches" (SU04)</i></p> <p><i>"I've had some problems logging on, quite a few problems actually. So I was supposed to be doing some, um, the questionnaires and things but I was thrown out quite a few times, so I contacted someone and then it took a bit time for them to get back to me, and then I've got to re get on again now and do another questionnaire. So I've had a few, well quite a few technical issues with it actually [...]so it's quite difficult because I obviously want to do the questionnaires but I can't do that. So I haven't really had the time to sort of chase it up as such to get it sorted out" (SU41 at 6-month follow-up)</i></p> <p><i>"They'd been trying to sort my, the online thing that we have, they tried to sort my password login thing, so I spoke to them probably about, I don't know, about six weeks ago just to re-do my login" (SU47 at 6-month follow-up)</i></p>
<p>One service user remarked that it would have been useful for clinic staff to be able to reset passwords when needed:</p>	<p><i>"Even now remembering stuff is difficult for me so passwords are quite hard... [Clinic staff] couldn't affect it or edit it which I think in some ways would have been a useful for them to be able to do to help me" (SU20)</i></p>
<p>Clinic staff recommendations</p>	
<p>Providing a clearer, detailed explanation behind the Predict test and information on how to use it</p>	<p><i>"One of the issues is with the faces test...and I think that probably could be solved with just explaining to people before they start, putting some kind of caveat around it so to say there's no right or wrong, to say it's fine if you miss one it doesn't matter, you know, see what the next one is. And there are lots of faces so it's looks like your overall perception so getting one wrong doesn't matter or getting ten wrong doesn't matter that's why there are so many of them" (KI01T2)</i></p>
<p>Consenting to taking part in research to be built into the app</p>	<p><i>"Can the research statement be part of the app? The faces test needed more information – what is was about and how to complete it, more video animations, reminders via text rather than email for users, improving the patient search function for GPs, only runs on particular versions of iOS. Having a statement on the app would be a better way of filtering out if someone doesn't actually agree with it... whether they could be booked in maybe in the week with time to see a GP" (FG01T1)</i></p>
<p>Ability to flag up if care plans are not set in the original meeting with the service user and to do so remotely</p>	<p><i>"If some of my other colleagues who haven't set them up with [service users], their care plans haven't been done which means the tests don't then flag because there's no entry of any medication being initiated. So they can't follow the protocol" (KI01T2)</i></p>
<p>Wider informant recommendations</p>	
<p>Introductory information, such as a video, on how to use the app and its functionality (this has largely been implemented already)</p>	<p><i>"I think there's more self-help that we could provide within the application itself to sort of, to if you like prompt and provide tips and hints of how to use the technology so that patients who are doing it on their own from home they have a little bit more, if you like they have someone, a virtual someone providing them some guidance and what to do and why they're doing what they're doing, to try and get them more engaged in what they're actually doing [...] We put more sort of video animations in, so we actually got some little videos which you can play which gives you a little bit more context, a little bit more understanding of what this i-spero app is, why you're using it. So I think there's more things we can do with what I would call the engagement education piece, which we're starting to look at now to try and make it easier to learn how to use the technology and get the most out of it" (WS01)</i></p>

Providing text alerts instead of email alerts	<i>"I think the other weakness is because we communicate reminders through email, we've already been looking at most recently also about texting because I think some people would probably rather receive a message by text than they would by email because they may not check their email very regularly...I think looking at other ways of providing that connectivity to a user and making it more personalised to what their needs are would be an advantage... So I think it's about engagement, it's about access and engagement I think are the two areas that I'd like to look to see if we could improve upon in terms of the application" (WS01)</i>
Service user ability to choose when the alerts are provided	<i>"Making it more personalisable by the patient I think would be another component, so that they, for example "I'd like to get my reminders at 8 o'clock in the morning" or "I'd like to get my reminders at 8pm in the evening", "I like to get them by text or by email", so they can choose, so each patient can choose what's best for them. Or they can say "I don't want any reminders", you know or, so I think making it a little bit more flexible that way would be good" (WS01)</i>
Allowing for a more diverse set of alerts, tailored to service user needs	<i>"There was a lot more alerts that [name] and I discussed and we decided not to implement some of them but actually I think some of them would have been valuable" (WS01)</i>
Enabling clinic staff to find service user records on i-spero in an easier, quicker way	<i>"One other change I'm just thinking about, that we should do that we haven't done is relating to being able to find patients more easily and more quickly" (WS01)</i>
Before i-spero becomes an app, ensuring that it can run on a wider range of operating systems	<i>"I would have been concerned about the platforms that it ran on. The fact that it would only run on particular versions of iOS" (WS02)</i>

Useful features

As well as making recommendations, respondents identified a number of features they found helpful. By far the most commonly mentioned useful feature among the **service users** was symptom tracking, which introduced the ability to see scores and symptom progression overtime:

"It was useful because it just helped to monitor how you feel and like I said before sometimes you don't necessarily recognise yourself that there has been an improvement in how you're feeling"(SU03)

I think it's actually just seeing the graph at the end of it to know, because you might think, 'oh yes it's been an alright week, same as last week', but actually when you look back your line's moved up or down and think you think, 'oh okay', it kind of makes you reflect on it as to what actually has happened. (SU69 at 6-month follow-up)

Service users emphasised the importance of the felt change in symptoms being backed up by scores and graphs on the i-Spero app, reassuring the users that the change was – in their words – a 'real' one. This was useful both as reassurance to the service user themselves, and in communicating illness progression to medical professionals:

“I’m a lot less depressed than I was, which is letting me get on with my day-to-day life. I’m back at work [...] it was a beautiful confirmation because about four or five days before I did the predict test I started to feel a lot lot better and then I did the predict test and it said that I’m now responding to the medication and it was a lovely sort of confirmation of what I felt about myself.” (IDC04)

“That’s been great, because I feel like the normal approach when you go to the doctor is they’re like, “How are things?” and it’s like, “Not great,” and maybe we could go out kind of the same as you came in, or maybe something’s just, you know, a dosage has been increased or whatever slightly, but this has been, it has felt like a more quantitative approach to it, because I’m like, I’m actually not feeling great, and look, this is how my questionnaire kind of indicates, it’s not just based on what I’m saying in a kind of, a short consultation, it’s also got that behind it as well” (SU33)

Service users also remarked on using symptom assessment questions as a platform for self-management (specifically concentrating on areas where the scores were lowest):

“I think it was really useful for me to be able to reflect on how I was doing and to monitor that myself and to kind of take a bit of ownership of it really. And to see actually I can see that I’m moving forward with things and things are feeling better. And also I think what’s really useful was in with the questions because as I do kind of like to reflect on things you could kind of see right ok what is it that I really need to work on?” (SU03)

“[S]o I’m also a numbers person. So actually both of those things lend me to trend analysis I guess so I’ve turned that in and on myself to see am I getting any better, am I not? It’s also helped me to characterise how I’m feeling both in myself but also in conversation with my family. And I’m going to use that for that purpose. I think for me that is the most beneficial part of it because a) I can start to reassure myself that I’m feeling a bit better when I am or if I’ve had a bad week, I’ve had a bad week and I can see either it’s a spike or a it’s a trend and therefore address it accordingly” (SU20 at 6-month follow-up)

“[S]eeing where I’ve sort of, I know I’ve sort of noticed a bit of a pattern, because I’ve got problems with my periods as well, so I’ve noticed a bit of a pattern with that as well. Because my mood drops, I’m having, I’m under the doctors for that at the moment as well, like my periods and stuff” (SU28)

The ability to evaluate via i-spero whether the service users responded well to medication has also been mentioned by many as a useful feature:

“It’s just been really useful to see how effective or not effective the medication is and the predictor test has kind of indicated to her that she needs to increase the medication or change the medication and she said that kind of it’s quite useful to do that and it means that I’ve kind of got onto a better medication perhaps more quickly than I would have done in other circumstances like without the test results” (SU03 at 6-month follow-up)

“I think we actually changed type again and then became that kind of indicated that things had improved but not really significantly then the doctor kind of played around with the dosage a little bit. And again that was, it was helpful because I didn’t have to wait, you know, six weeks and then go back and say, I think things are better or worse, etc, it was done much quicker” (SU33)

However, one respondent spoke about the Predict test suggesting a change in medication despite an improvement in symptoms on PHQ-9 and GAD-7, and the resulting confusion:

“I was doing the sort of weekly questionnaire to kind of monitor my progress. And so it was, I mean the software was sort of saying that I would be better off on another medication. Which was kind of, I thought that was a little bit strange because according to the chart I was starting to improve” (SU01)

While this was mentioned fewer times than the usefulness of symptom tracking, many service users commented on the importance of app integration within the clinic and ability for GPs to remotely monitor scores:

“I think if the app wasn’t linked to the doctor it probably wouldn’t have got my attention to start with. Because if I felt that nobody else was looking at it then it would be one of them things that I’d maybe do a couple of times and then nobody checked in, nobody asked any questions and I just didn’t do it again” (SU47)

“I guess alone it’s very similar to other mood trackers, but as an app that’s linked into your GP and like your actual medical care I would recommend it to others, if their surgery was running, you know, a service where their GPs were able to look at this and use it then I would definitely recommend it” (SU33)

“I think it’s really important and I love the fact that Dr. [name] can see how I’m doing because she’ll ring me up and like the last time she rang me up because she can’t see [my scores]” (SU36)

Some service users stressed that the app enabled the GP to get in touch with them sooner than they would have otherwise reached out for support, ensuring prompt treatment and preventing avoidable deterioration:

“I unfortunately had a relapse back in December and Dr. [name] at the clinic instantly spotted my scores. I went in that next weekend and she was expecting me because she knew my scores had gone down from looking through the app and she was just absolutely fantastic” (SU04 at 6-month follow-up)

Medication and other reminders were useful to many service users, too:

“I’ve found the system an excellent reminder. Very kind, you know, the points like alcohol or exercise, very good reminders. It’s not, I don’t feel pressured by it at all” (SU44)

The care planning function was mentioned least frequently as a useful feature, but some service users found these features helpful:

“I have seen the other aspects of having goals and targets and the reminder to take the medicine etc. They’re less valuable to me in some ways because I’ve become reasonably regimented” (SU20)

“You can monitor everything: you can monitor your exercise; your medication; you can put appointments on there it reminds you; it emails you appointment reminders” (SU29)

Clinic staff or wider informants did not frequently remark on app features. Some have stressed the self-monitoring aspect, where the use of i-spero also enabled patients to visualise this progress as evidenced by qualitative data:

“I’d say for a lot of people they like it. I think the really nice thing is that they can see whether they’re improving or not themselves” (FG01T1)

“You just need to look at the scores and you can see people are improving... I think that’s actually boosting the confidence of the staff because they can all see that, and it makes them feel proud that they are helping people” (FG02T1)

“The great thing is, you know, we can see from the results that it’s working and I think that’s really the main thing is getting the data to validate that this clinic is working, you know, and the software is evidencing that...with the graphing and the scores and the data...to qualify the drugs and treatments that are being used, to qualify that there has been a proven improvement” (WS10)

Others have spoken about the importance of suicide alerts which allow GPs to work more proactively – they can speak to the patient immediately, refer to secondary care if necessary.