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'Care Co-ordinator In My Pocket'. A Feasibility study of Mobile-Assessment and Therapy for Psychosis (TechCare).

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Abstract

Objectives: The research aimed to examine the acceptability and feasibility of a mobile phone Application (App) based intervention 'TechCare', for individuals with psychosis in the North West of England. The main objectives were to determine whether appropriate individuals could be identified and recruited to the study and whether the TechCare App would be an acceptable intervention for individuals with psychosis.

Methods: This was a mixed methods feasibility study, consisting of a test-run and feasibility evaluation of the TechCare App intervention.

Setting: Early Intervention Services for psychosis, within an NHS Trusts in the North West of England.

Participants: Sixteen participants (Test-run n=4, feasibility study n=12) aged between 18-65, recruited from the East, Central and North Lancashire Early Intervention Service (EIS).

Intervention: A 6-week intervention, with the TechCare App assessing participants' symptoms and responses in real-time and providing a personalised guided self-help based psychological intervention based on the principles of CBT.

Results: A total of 83.33% (n=10) of participants completed the 6-week feasibility study, with 70% of completers achieving the set compliance threshold of $\geq 33\%$ engagement with the TechCare App system. Analysis of the qualitative data suggested that participants held the view that the TechCare was both an acceptable and feasible means of delivering interventions in real-time.

Conclusion: Innovative digital clinical technologies such as the TechCare App may have the potential to increase access to psychological interventions, reduce health inequality, and promote self-management with a real-time intervention, through enabling access to mental health resources in a stigma-free, evidence-based, and time-independent manner.

Trial registration number: ClinicalTrials.gov Identifier: NCT02439619

Background

The use of mobile devices (e.g. mobile phones) within healthcare interventions, referred to as mHealth, is a growing field globally with the potential to improve mental health. Research in the area of mHealth, has indicated scope to facilitate the development of mobile phone interventions which look at the assessment and treatment of psychiatric disorders in real-time (Ainsworth, Palmier-Claus, Machin, et al., 2013, Bucci et al., 2018, Spaniel et al., 2012 & Granholm, Ben-Zeev, Link, Bradshaw, & Holden, 2012). The use of mobile devices could provide greater autonomy to service users (Palmier-Claus et al., 2013) some of whom otherwise may be seen as a 'hard to engage group', with complex relationships between psychotic experiences, trust and engagement with services. mHealth may be able to offer a non-stigmatising approach to treatment through providing a discrete medium for seeking support which can be both accessible and anonymous, as many service users may experience mental health stigma (Inal, Wake, Guribye & Nordgreen, 2020; World Health Organization, 2019; Cotton, 2019), which can compound difficulties with engagement, treatment adherence and thus outcomes.

Early Intervention services (EIS) were introduced into the NHS in the early 1990's, for people with a first episode of psychosis (Lester et al., 2011; Allard et al., 2018; Park, McCrone & Knapp 2016; Birchwood & Singh, 2013). The primary aim of EIS's was to reduce the Delay in Untreated Psychosis (DUP), with the rationale being that early treatment of psychosis could result in a greater chance of recovery, and a reduction in the adverse psychosocial impact of the illness (Reichert & Jacobs 2018; McGorry et al., 2008). Previous research has shown that these services are cost effective, and are successful in reducing relapse, leading to reductions in hospital admissions (Tsiachristas et al., 2016; McCrone, Craig, Power, & Garety, 2010).

Digital technologies which include self-help strategies promoting service user autonomy and control, may potentially assist in making the resources of EIS go further, supplementing face-to-face practitioner time with service users. This is important due to the increasing levels of pressure on mental health services as a result of substantial reductions in resources dedicated to mental health services (Docherty & Thornicroft, 2015). There are waiting lists to receive psychological therapies in many EIS, mobile technology may be an alternate way of engaging and supporting the service users, by enhancing self-management and increasing the accessibility of psychological support. The TechCare App was thus developed to provide real-time therapy (Kelly et al., 2012; Husain et al., 2016) targeted at reducing symptoms of psychosis, allowing appropriate interventions to occur in real-time and thereby reducing the possibility of relapse. Improving the access to digital clinical technologies particularly in low resourced or deprived localities can be of great benefit in providing a step-change in the utilisation of low-cost mobile technologies (Naslund et al., 2017).

This study looked to integrate a momentary sampling assessment approach that is matched with a momentary basic psychological intervention to address low mood and paranoia. This may address the huge treatment gap in mental health care by potentially increasing access to psychological interventions. This feasibility work intended to inform the design of a larger trial, which would examine important parameters such as, the identification of appropriate outcome measures, follow up periods and estimates of recruitment and feasibility of the TechCare App intervention.

Aim: The aim of the project was to develop and conduct a feasibility study of the mobile phone application (App) 'TechCare' for individuals with psychosis in the North West of England.

The specific objectives of the research were to:

1. To determine whether a small sample of eligible (N=16) individuals could be identified and recruited to a study for the evaluation of TechCare for psychosis
2. Whether TechCare would be an acceptable intervention for individuals with psychosis? This will be determined by qualitative interviews.
3. Whether service users can they be engaged in setting goals and reporting outcomes to their care coordinators and work towards the goals using TechCare App. This will be determined by the extent of engagement with the app.
4. Establish the most appropriate primary outcome measure for a future randomised controlled clinical and cost effectiveness trial (RCT) of the TechCare intervention. This was to be determined by the ease of use assessment measures and participant preference.

Methods

Study design

The feasibility study followed the National Institute of Health Research (NIHR, 2014) guidance on feasibility study design and used a mixed methods approach. This was a feasibility study including test-run and qualitative semi-structured interviews. The TechCare App assessed participants' symptoms and responses and provided a personalised guided self-help based psychological intervention, with the aim of reducing participants' symptoms and enhancing their coping abilities. An initial, test-run with a small number (n= 4) of participating service users was conducted, to refine the mobile App intervention (TechCare) and address any issues found in the App software, content and design, based on participant feedback. The TechCare App was then evaluated as part of a feasibility study with a total of n=12 service users. In addition, a total of 16 pre-intervention qualitative interviews and 13 post-intervention interviews were completed. The study was pre-registered on ClinicalTrials.gov Identifier: NCT02439619 and ethical approval was obtained from the NRES Committee North West - Preston REC reference: 14/NW/1192.

Participants

The sample for the study was recruited from the East, Central and North Lancashire Early Intervention Service (EIS) for Psychosis Teams in the North West of England. Potential participants were volunteers who had already shown interest in the study, plus additional service users, carers and EIS Care Coordinators were invited to take part in the study. The participants, who took part in the test-run and feasibility study, were individuals under the care of the EIS. The inclusion and exclusion criteria for the study are as follows:

Inclusion Criteria

- Each service user must have been accepted into the Psychosis Group of the Lancashire Early Intervention service.
- Age 18 – 65 years
- Medication stable for the previous two months - [REDACTED] [REDACTED] uses a traffic light system to indicate current symptomatology and risks of each client. For this study we only included service users with a Green Light, signifying that their mental state was stable.
- A score of 3 or more on positive symptoms on the Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987)

- Minimum score of 1 on the Calgary Depression Scale (CDS) (Addington, Addington & Schissel, 1990)

Exclusion Criteria

- Patients with drug induced psychosis, an acquired brain injury or moderate to severe learning disability, as determined by the service users treating clinician.
- Service users who are undergoing assessment, not formally diagnosed and accepted into the service.
- Lacking capacity for informed consent.
- At Risk Mental State (ARMS) group (i.e. Prodromal, not first episode)

Defining the Intervention: Experiential Sampling Methodology (ESM) & Intelligent Real-Time Therapy (iRTT)

The TechCare App software was developed specifically for use on a smartphone device, requiring a touchscreen interface. The mobile phone (App) Application would alert participants via notifications and ask a series of questions. Based upon the participants' responses, the App would provide a tailored CBT based interventions, and could include participants preferred multimedia such as, music, images or videos. The App used ESM as a research methodology which allowed participants to record, subjective experiences in real-time of their thoughts, moods and experiences of distress. The ESM research methodology was coupled with intelligent Real-Time Therapy (iRTT) which is a conceptual model developed by Kelly et al., (2012) that uses the data gathered by ESM on a participants subjective experiences of distress and in response provides interventions to be delivered in real-time. iRTT may comprise of several formats, including media, images or MP3 formats which were all integrated in the present study.

Three notifications were sent between the time points, 10am and 10pm each day over the study period. If the App detected low mood/paranoia, participants were offered tailored interventions based on the iRTT model. The system would then re-notify the participants a total of three times, every 60 minutes if low mood/paranoia was detected over a period of ≈ 4 hours. If symptoms persisted for greater than 4 hours, this would initiate a prior agreed crisis response being displayed on the App. Crisis planning is a routine part of EIS treatment, where service users would work collaboratively with their care coordinators to agree a plan of action to follow, when in crisis. When symptoms are exacerbated causing severe distress, the crisis response may include contacting the EIS or an agreed designated contact. In the feasibility context, an examination of the response rates to the questions and notifications were observed including the participant's selection of intervention.

The TechCare App ESM and iRTT system utilised intelligence at two levels. The first level involved recognising and intelligently increasing the frequency of assessment notifications if low mood/paranoia was detected. This was done via feedback loops monitoring symptoms over time and the deployment of a tailored crisis plan if there was a prolonged period of low mood/paranoia detected (≈ 4 h). The second level included an intelligent machine learning algorithm, providing interventions in real-time when assessment thresholds were exceeded (e.g. when levels of paranoia exceeded a certain threshold), thus providing recommendations on the most popular interventions selected by the cohort of participants on the study, listed in rank order. See Husain et al., (2016) for further details of the methodology.

Outcome Measures

The primary aim of the study was to determine the feasibility and acceptability of the TechCare App intervention. This included, measuring whether eligible individuals could be identified and recruited to a feasibility study of the TechCare App. The success criterion for feasibility was the recruitment of $\geq 50\%$ of eligible participants, based on the recruitment rate of previous research using the ClinTouch system (Palmier-Claus et al., 2012) which this study was based on. In addition, the acceptability of the intervention was assessed based on the amount of engagement and usage of the TechCare App, with the success criterion for compliance being set at $\geq 33\%$. In the ClinTouch study (Palmier-Claus et al., 2013) compliance was calculated as engagement with 33% of the available notifications. In addition the following outcome measures were used; Positive and Negative Syndrome Scale (PANSS) (Kay et al., 1987), Psychotic Symptom Rating Scales (PSYRATS) (Haddock et al., 1999), Satisfaction with CBT therapy on the CHoice of Outcome In CBT for psychosis (CHOICE) (Greenwood et al., 2010), Mental wellbeing on the Warwick-Edinburgh Mental Well Being Scale (WEMWBS) (Tenant et al., 2007), Measure of core beliefs regarding self and others on the Brief Core Schema Scale (BCSS) (Fowler et al., 2006), Depression on the Calgary Depression Scale (CDS) (Addington, Addington & Schissel, 1990), Work and social functioning on The Work and Social Adjustment Scale (WSAS) (Mundt et al., 2002) and Quality of life on the EuroQoL-5 Dimensions (EQ5-D) (Sobocki et al., 2007) to determine the most appropriate outcome measures for a future clinical and cost-effectiveness trial.

Data Collection & Analysis

As this was a mixed methods feasibility study both quantitative and qualitative data was gathered and analysed. The quantitative data collected as part of the study is presented using summary statistics (SD, Mean, Confidence Intervals). Preliminary analysis was performed to compare the baseline and post-intervention scores on the outcome measures. In the feasibility context, data on recruitment and retention was calculated, with the iRTT data gathered allowing for the analysis of participant responses and the selection of interventions during the trial. Semi structured interview were conducted using a topic guided to collect the qualitative data. The digital semi-structured interviews were transcribed verbatim and framework Analysis was used to analyse the data (Ritchie, Spencer, Bryman, & Burgess, 1994). The Framework Analysis started with the process of familiarisation, where data from all transcripts was read a number of times to gain an understanding and familiarity with the content, the next stage of the analysis involved key Ideas and themes that were recurring being noted, with the final themes being compiled into a thematic framework. The Framework Analysis was conducted to look for emerging themes, focusing on feasibility, acceptability and further development of the intervention.

Results

Test-Run Results

Feedback from participants in the test-run provided insight into the refinement and further development of the App, both in terms of the intervention content and design and the research process and procedures. A total of 4 participants took part in the test-run, with 3 participants being male and 1 female. The mean age of the participants 22.5 years old ($SD= 4.39$). We examined any software difficulties or faults that occurred during the test-run. The software code was monitored by the software engineers, with errors in the code being sourced and corrected. Changes in the software was mainly in relation to ensuring the notification system was working correctly, and the screen size and login system was appropriately configured.

Feasibility Results:

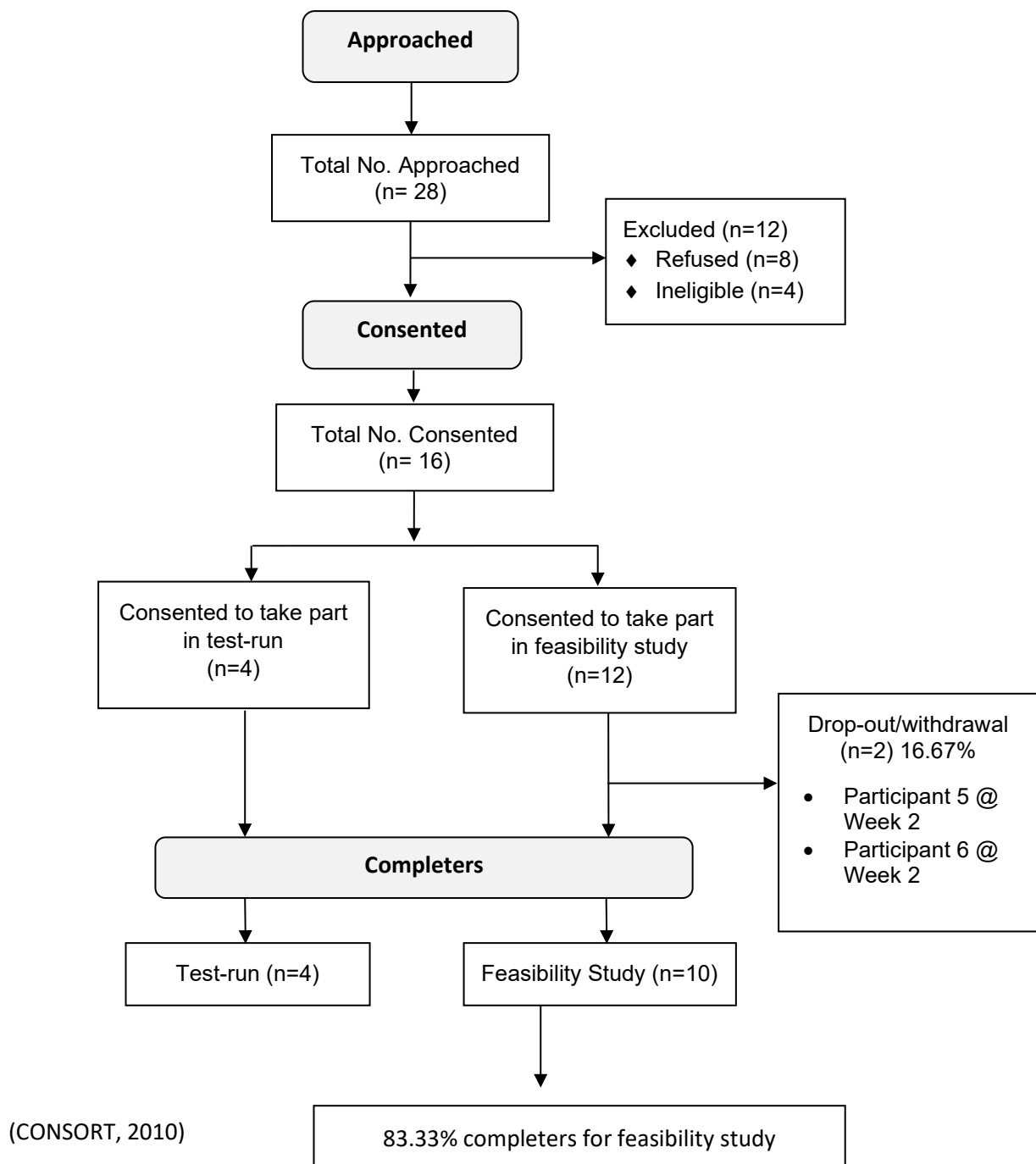
A total of n=28 participants were approached to take part in the study with n=16 consenting to take part, however two participants dropped out. One participant was unable to continue on the study at week 2 due to not being concordant with medication, and one participant decided to drop out at week 2 due to not wanting to proceed. No explanation was given as to the reasons behind the latter drop out. The recruitment rate was calculated at 57% of the total number of participants approached in the study. Overall, 83% of those who consented to take part in the feasibility completed the study Figure 1 shows recruitment and retention rates of both the test-run and feasibility study.

The feasibility study sample comprised of 12 participants, all participants were aged between 25 - 40 years. The mean age of the participants was 24.83 year (*SD*= 4.83). The sample consisted of 8 males and 4 females, 9 were unemployed, 7 were single, with all 12 having access to the internet. All but one had access to a smartphone phone, with the participant being loaned a mobile phone for the duration of the study (See Table 1).

Table 01. Demographic for Participants in the Feasibility study

Feasibility Study		Total
Gender	Male	8
	Female	4
Age	Mean Age	24.83
	Range	19-35
Ethnicity	British - White	8
	British - Indian	2
	British - Pakistani	2
Work	Self-employed	0
	Part-time employment	1
	Unemployed	9
	Student	2
Living situation	Living with family	10
	Lives on own	1
	Lives in shared accommodation	1
Marital Status	Single	7
	Partner/Married	4
	Separated/Divorced	1

Figure 01. Flow diagram to show Recruitment and Retention



Acceptability: Engagement and Usage of the TechCare App Intervention

The TechCare system notified the participants 3 times per day (A minimum of 126 notifications over the 6-week period). Compliance was based on engagement with the App, at least, a total of 42 times over the study period ($\geq 33\%$). It was found that the out of the 12 participants, eight (66.67%) achieved compliance, however this figure takes into account the two participants who dropped out after week 1. On removing these two participants, out of the 10 remaining participants a total of 70% achieved compliance, related to answering the TechCare App questions.

The interventions screen was shown a total of 82 times across the 6-week period with the most selected intervention being the multimedia intervention. Data collected from the online server provided insight into the day-to-day usage of the App by each of the participants. There were a number of key variables that were analysed to provide a descriptive account of the App usage across the feasibility study period. Overall we found that out of the 12 participants the App was registered and loaded a total of 947 times with participants using the App on average 1.88 times per day..

The TechCare system also allowed for the collection of patient derived response data through the TechCare App. The data was scored on a 1-7 Likert scale, with 1 being completely disagree and 7 being in full agreement with TechCare App questions related to symptoms of low mood and paranoia (See Husain et al., 2016). The average weekly score in week 1 for the Depression scale was $M=29.13$ ($SD=18.29$) and for week 6 was $M=17.50$ ($SD=11.92$), which indicates a decrease in depressive symptoms from week 1 to week 6. Furthermore, there was a similar trend on the paranoia scale, with the average score decreasing from week 1 ($M=38.00$, $SD=28.27$) to week 6 ($M=33.92$, $SD=27.88$) On further analysis of the notification data gathered it was found that out of the daily 3 notifications over the 6 week period, the mean score of for the depression scale questions was 2.66 ($SD= 1.90$) and for the paranoia question scale questions was 2.71 ($SD=1.75$). On analysis of the notification system data it was found that over the 6-week period, participants clicked on the notifications a total of 521 times with the average number of questions completed by participants being 5.63 times per day (Range: 0-25). . Furthermore, it was found that the participants used the self-help material a total of 114 times. This was the psychoeducational information tab located on the home screen. These findings suggest engagement with the App and the feasibility of the system. One interesting finding from the results was that none of the participants reached the threshold for the crisis intervention.

Weekly Assessment Results:

In addition to the pre- and post-intervention measures, face-to-face weekly assessments were conducted with the participants (see Table 2). The weekly outcome measures were collected over the 6-week intervention period. It can be seen that there was a reduction in mean scores over the 6-week period on the CDS. However, the other weekly measures examined suggested that there was a decrease in scores until week 5, with week 6 scores increasing slightly. Furthermore, the assessment scores seem to decrease from weeks 1-3 then plateau during weeks 4-6. This may have been due to increased interest and engagement with the App during the beginning of the intervention period (Weeks 1-3) and this diminishing over the latter half of the intervention period (weeks 4-6).

Table 02. Table to show Mean and Standard Deviations for the Weekly Assessment Measures

		<i>Calgary Depression Scale</i>	<i>Brief Core Schema Scale Negative Self)</i>	<i>Brief Core Schema Scale (Positive Self)</i>	<i>Brief Core Schema Scale (Negative Self)</i>	<i>Brief Core Schema Scale (Positive Other)</i>	<i>Work and Social Adjustment Scale</i>	<i>Warwick- Edinburgh Mental Wellbeing Scale</i>	<i>Choices</i>	<i>EQ5-D</i>
Week1 (Baseline)	Mean	9.06	8.00	5.17	9.42	9.42	20.44	37.94	48.06	5.75
	Std. Deviation	5.51	5.58	4.58	7.34	5.59	10.23	10.39	30.02	2.64
Week 2	Mean	5.75	5.40	7.50	8.50	7.50	17.94	33.69	60.56	10.88
	Std. Deviation	5.80	5.32	5.09	7.88	5.77	11.50	16.04	58.62	23.62
Week 3	Mean	6.06	7.00	8.56	9.22	10.00	17.25	33.69	55.19	9.66
	Std. Deviation	5.80	7.91	4.95	8.59	6.12	12.16	20.11	45.66	24.00
Week 4	Mean	2.63	5.44	7.44	6.56	12.33	12.25	21.81	31.00	3.26
	Std. Deviation	4.43	6.56	5.09	7.55	7.28	13.85	21.30	33.33	3.29
Week 5	Mean	2.13	2.88	11.88	5.25	12.71	8.69	23.88	34.00	3.73
	Std. Deviation	3.50	4.05	3.40	6.85	5.70	11.66	25.54	38.90	3.87
Week 6	Mean	2.13	5.80	10.00	7.30	11.70	11.13	27.75	39.88	4.08
	Std. Deviation	3.32	7.31	6.31	7.68	6.90	13.38	24.57	40.45	3.64
Totals	Mean	4.63	5.97	7.78	7.96	9.77	14.61	29.79	44.78	6.22
	Std. Deviation	5.37	5.57	4.70	7.25	5.58	12.59	20.62	42.48	13.97

Qualitative Study Results

Pre-Intervention Qualitative One-To-One Interviews with Service Users

The qualitative interviews investigated the feasibility and acceptability of the intervention. Overall, the key themes that were identified on the analysis of the pre-intervention qualitative interviews (n=16) were organised into a coding framework as follows: accessing support for psychosis, mobile phone usage and ownership, the acceptability of the TechCare intervention, confidentiality and security and finally the areas of development and refinement of the App.

1) Accessing support

This theme presents participants' views regarding accessing support for their mental health difficulties, specifically highlighting complications and problems in accessing support. The theme explored the individuals' experiences of various factors that impede access to appropriate and valued support. These include failings in support and limited access to services, a lack of understanding of their needs, the role of stigma in accessing services, and experiences of isolation. Throughout, the participants focused attention to possible benefits that a helpful mobile App might generate in addressing the above difficulties

"P10: I found in the past that... to be able to get the right help that you need is very difficult because you have to end up going through so many different people, it sometimes weighs you down until you get to the right person"

"P4: I had names called because of illness...a phone is discrete no one will know"

"P8: It's a good idea yeah, because like you said there's a lot of stigma around it, with mental health issue, like people start looking at you differently"

2) Mobile phone usage

This theme portrayed the feeling that although mobile devices were an important part of day-to-day life, there was a need for moderation in general day-to-day usage. Mobile devices were reported to be easily accessible, with all participants engaging in mobile phone usage throughout the day. This inferred that mobile devices could potentially be a familiar medium for accessing support. Furthermore, the participants also talked about the financial implications of mobile ownership and connectivity to the internet.

"P16: Texting is easier, sort of still need face-to-face as it helps to build a dialogue and is empowering"

In addition, social media was found to be mostly a useful aspect of the experience of going online, however there were some concerns that you could post things online and be judged by people.

3) Acceptability of the TechCare App intervention

The App was described as a 'brilliant idea' by participants, and that treatments delivered in this way would be acceptable. All participants provided feedback suggesting that they did not envisage service users in general being averse to using the TechCare App. However, factors such as the App layout and design features were crucial areas for consideration.

"P3: [TechCare Logo] it's like anonymous, you can't tell... You can't tell what it is, if it was like a medicine sign people would know what it means"

4) Confidentiality and Security

Participant views relating to confidentiality were also discussed in the one-to-one interviews. There was specific reference to the security access on the device and how it can have an impact. In addition, it was recommended that having a privacy policy on the App would provide further details on the confidentiality arrangements of the intervention. Having this explained by a health professional would help reassure service users about the confidentiality of data.

"P9: Umm because I know some people like me who might not want our information to be [shown] to everybody.....um I think if it was explained by a care worker or...yeah umm maybe have the privacy policy on the App"

"P12: Confidentiality, you should put like a password on or something"

5) Areas for development and refinement of the App

There were a number of ideas proposed by the participants in relation to the further development and refinement of the App. Some of the areas suggested by the service users were; enabling personalisable settings within the TechCare App, inclusion of helpful websites, suicide prevention support helplines, calendar reminders for medication and appointments with health professionals, the ability for service users to note down how they are feeling using the App, and information on mental illness and medication side-effects.

"P15: For medication reminders maybe, I need like a video of the service so you know what to expect"

"P8: Yeah I suppose. Sometimes I struggle like it's when, like a week or whatever between my appointments, its hard work remembering things that have gone on, so I suppose it keeps you up to date, it keeps it live like"

In addition, there was a general consensus that service users had a limited understanding of psychosis and had difficulties in explaining their experiences to family and friends. Recommendations were made to include helpful information on the App relating to gaining a better understanding of psychosis.

"P4: People's experiences/stories what other people are going through"

"P9: Things like videos explaining mental illness"

"P8: When I got diagnosed with psychotic disorder I looked it up online and there are loads of psychotic disorders, so I was thinking which ones me....it's just all very broad and vague"

Other development and refinement ideas presented by the participants centred around the inclusion of coping strategies and motivational pictures.

"P16: Coping strategy information about medication side-effects"

"P9: Yeah I think there is a positive side to it, for example like motivational pictures. Things like pictures like that have motivational quotes on them"

The findings from the pre-intervention qualitative work informed the further development and refinement the TechCare App in preparation for the feasibility study.

Post- Intervention Qualitative Interviews with Service Users

On completion of the Test-run and feasibility study, follow-up one-to-one interviews (n=13), were conducted. Participants provided feedback on the overall acceptability of taking part in the TechCare research study, with the experience being enjoyable and empowering.

1) Acceptability and Feasibility

The participants provided their views relating to their experience of using the App and the consensus was that it was an acceptable method for receiving psychological interventions. The views on research related procedures included length of time taken to complete assessments and the research recruitment procedures, which were considered acceptable.

"P12: Overall, I think the App was a really good idea, it's a new way of doing treatments and it works alongside your medication"

"P15: The process of the using the TechCare App was empowering and was an achievement as I normally struggle to come outside"

2) Usability and User Experience

The usability of the device in terms of its day-to-day usage was found to be easy to manage with particular reference to the easy navigation of the TechCare App. This was suggested to be an important factor in the App usage. It was also highlighted that the psychoeducational links were a useful tool to understand specific information on psychosis.

"P12: It was very easy to use, very easy, very simple, there wasn't any obstacles using it or anything, think it was made very simple, which is a good thing"

"P9: Yeah like the time taken to complete the questions...I liked how quick it was"

3) Accessing and engaging with support

The participants view was that having easy access to information and useful contact details provided an avenue for participants to seek help. The availability of help through the App was seen as a prompt for service users. The participants reported that the App was used at times when they experienced distress associated with their illness, thus providing greater autonomy and more choice. Talking about mobile devices was suggested to be an important means of starting conversations and providing an alternative way of communicating with health professionals. Although the App was seen as an important tool in accessing support in real-time, the participants were of the view that face-to-face contact was an integral part of the care they received from the EIS service.

"P11: Understanding the thoughts, helps start conversations and stuff just for the fact that I ended up with a new phone just to use for the time being, just started conversations"

"P10: Having a face-to-face interview can explore different things like why you are actually feeling down and stuff"

4) Suggestions for improving the TechCare App Intervention

The participants offered a number of suggestions to improve the TechCare App. The improvements related mainly to the App content, such as incorporating calendar and in-App progress tracking. It was highlighted that mobile technology was part of the future, in providing support for individuals with mental health difficulties, but it was not the whole picture. The areas of improvement included novel

Ideas such as inclusion of newsfeed where people with similar experiences could comment on strategies they had used and benefitted from:

"P4: News feed so other people can respond to it like when I'm feeling down I do this"

"P15: The functionality, asking questions tracking the feedback....have reminders early in the day"

5): Insights into the iRTT system

A key area of focus was testing the Intelligent Real Time Therapy (iRTT) concept. In the view of participants, a number of interventions were used. Some of the more popular interventions used were multimedia, problem solving and the use of links to mental health support websites and psychoeducation. The participants held a consensus view that the iRTT system had allowed them to gain insight into their experiences and allowed them to manage their symptoms.

"P12: Before I was depending a lot on [Care coordinator] all the time, whenever something went wrong, but since I got the app, it's been like I have a care coordinator in my pocket, so it felt like there was a mental health professional in my pocket, so whenever I have like a problem I just go on the screen and it would give me solutions which I don't think about at the time... now I don't rely on the App as much, because I've kind of programmed it in my mind, how to, like if I'm facing difficulties how to step-by-step break the problem down"

"P13: Helped organise my thoughts.... Helped me to understand...What I was going through"

Overall, it is important to note that participants considered the TechCare App intervention to be acceptable and feasible intervention. The research procedures and processes were also acceptable. The participants gave examples of how the App had assisted in their personal recovery journey. However, it should be noted that the project involved weekly assessments which offers an opportunity for greater levels of engagement with participants.

Discussion

The study provided insights into the development of mHealth interventions for psychosis which used the iRTT conceptual model. The main objectives of the study related to determining the recruitment, retention, and drop-out rates of participants and engagement with the TechCare App intervention. The results of the study met the success criterion for feasibility and acceptability of the TechCare study. Overall, the key finding of the study was the acceptability and feasibility of use of the TechCare App and study design, as well as the methods for evaluation. The availability of the intervention in real-time, in contrast to limited face to face time with the therapist and the flexibility in the use of the intervention, could be seen as a potential advantage, however a significant proportion of the participants held the view that this should be in addition to the face-to-face contact (rather than a replacement).

Support for these findings come from a study by Lester et al., (2011) showing the importance of technology in engagement within EIS. This is important in drawing emphasis on how mHealth functions could provide continued support, but also give service users an opportunity for self-management. Indeed, future research may determine the value of mHealth for different groups of service users, distinguishing between service users who engage with services or more self-reliant refusers of services for example. It may be that mobile technologies offer different forms of value to each group, with the former responding similarly to participants in this study and the latter, may prefer

utilising technologies to maximise autonomous independence from services. Both scenarios raise questions about the nature and experience of self-management in the context of services operating within the current austerity climate of the UK.

In addition, another important finding of the feasibility study was that none of the participants reached the threshold for the crisis intervention, which may have been due to inclusion of participants who were deemed clinically stable by their care team, or due to the questions that were asked not being sensitive enough to pick up issues such as boredom with the App or lack of perceived benefit over the 6-week period.. It is important to note the data collected in real-time, provided an insight into the day-to-day experiences of the participants, with TechCare providing a flexible and tailor-made self-help intervention, if low mood or paranoia was detected. Participants were able to use this data retrospectively to recollect events in the past week, providing the service user participants greater insight into their experience of their illness. Current services often expect service users to retrospectively recollect experiences over the preceding week or further back. However, often due to the distress experienced by service users, difficulties in recollection of experiences can occur and difficulties in communicating distress, have been found to be a confounding factor when undertaking therapeutic work in psychosis (Byrne & Morrison, 2010; Palmier-Claus et al., 2012). The TechCare App provided an alternative means to record the participant's experiences, and allowed health professionals to view any changes in the symptomatology of the service users, thus overcoming difficulties in recollection of experiences. The results of the study support previous research (See Oorschot et al., 2009; Kimhy, Myin-Germeys, Palmier-Claus & Swendsen 2012; Myin-Germeys, 2009), with Experiential Sampling Methodologies (ESM) being used as an important means of gaining understanding of the real-world socio-environmental factors related to psychotic symptoms.

Strengths and limitations of the research

The main strength of the study was the feasibility testing of a novel intervention for psychosis, which used the iRTT conceptual model (Kelly et al., 2012). To our knowledge iRTT has not been evaluated in an early intervention setting before and as such, the study provided novel insights into the development of mHealth interventions. A Further strength of the study was the engagement of the service users, across the study period with only two participants dropping out. In addition, as we chose a pragmatic approach to the research, which was conducted within the NHS context, this allowed the TechCare App to be feasibility tested as a pragmatic solution to increase access to psychological therapies. There was good retention with participants meeting 83% of all follow-up data points.

The major limitation of the study is the relatively small sample size for the feasibility study. Across the study period, we recruited a total sample of n=16. Previous research in the area of feasibility studies has indicated a range of sample sizes. Billingham et al., (2013) reported a sample size range for feasibility studies from 10 to 300 participants (median = 36, range). We fall in the lower range and the study would have benefitted from a larger sample size. Although the results of the qualitative work were promising, we present these with caution given the multiple factors associated with routine treatment. A further limitation of the study was the lack of a randomised controlled trial design, the addition of a control arm would have provided beneficial insights into the acceptability in relation to allocation and randomisation procedures. We found no adverse events experienced by the participants in the study. This could have been due to the safety considerations made in conjunction with participants' case managers when making referrals to the study and the continued involvement during the study indicating a potential selection bias. However, it is important to note that due to the developing nature of the mHealth field and relatively limited evidence base on the side effects of mHealth Apps (Naeem et al., 2016), the adverse events may not have been apparent. The study was

in only one early intervention service therefore the results cannot be generalised to other EIS's in the country.

Conclusions

Innovative digital clinical technologies such as the TechCare App may have the potential to increase service access, reduce health inequality, and promote self-management with a real-time intervention. The mobile intervention may also support medication adherence and appointment attendance, in addition to recognising early warning signs both by the participants themselves and also their EIS case managers. The concept of self-management and self-help are interesting in that they appear to chime in with a valuing of independence and individual autonomy that fits well with a recovery ethos within healthcare services. Staff and service users emphasised a balance between the positive aspects of self-reliance, a more collective, network based psychosocial support system, and a continued value of face-to-face therapeutic relations with skilled health professionals. mHealth can play a major role in low resourced settings especially in areas where there is limited funds and resources to spend on healthcare. Measuring trends and analysing real-time real-world data may also allow for better forecasting and ensure measures can be put in place to improve clinical practice and more efficient use of limited resources. Following this feasibility study, relevant alterations will be made to TechCare with the aim of conducting a larger scale clinical- and cost- effectiveness Randomised Controlled Trial (RCT).

List of Abbreviations

mHealth	Mobile digital health technologies
App	mobile phone application
EIS	Early Intervention services
DUP	Delay in Untreated Psychosis
CBT	Cognitive Behavioural Therapy
iRTT	intelligent Real-Time Therapy
ESM	Experiential Sampling Methodology

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Contributors

NG, NH, IBC, JK conceived the idea. MM, JD, NC, NM contributed to the design of the project. NC, NM, PJT, FN helped develop the research tools. NG led data collection and oversaw the recruitment process. NG, MM led the analysis of the qualitative data and quantitative data. NG, MM, NH, IBC drafted the initial manuscript. All authors read and approved the final manuscript.

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Competing interests

[Add]

Patient consent for publication

Not required.

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Ethical Approval was obtained from the NRES Committee North West - Preston REC reference: 14/NW/1192.

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Data sharing statement

The quantitative dataset is available upon reasonable request from the corresponding author.

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