Adherence in mobile and web-based technologies for people with psychosis

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Systematic Literature Review

Empirical Research Project

Service-Related Project

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Chapter 1: Systematic Literature Review

Adherence in mobile and web-based technologies for people with psychosis

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Abstract

Background: In order to advance and build on the recent boom in mobile and web-based interventions for individuals with psychosis, a better understanding of current levels of adherence and predictors of adherence to mobile and internet interventions is required.

Method: This paper systematically reviews rates of adherence, dropout and approaches to analyzing predictors of adherence to newly developed mobile and web-based interventions for people with psychosis. A systematic review of randomized controlled trials, feasibility trials and observational trials is presented. We also examine three theoretically proposed predictors of adherence; level of social support present in the trial, level of service user involvement and type of study.

Results: All the included studies (n=17) reported a measure of adherence and a rate of dropout. The studies varied in terms of their further analysis of adherence; five studies conducted statistical analyses to determine predictors of dropout, five studies conducted analyses on specific predictors of adherence to the intervention, four administered post-trial feedback questionnaires to assess continued use of the intervention, and two studies evaluated different types of interventions with the aim affecting adherence. Overall the percentage of participants adhering to interventions ranged from 60% to 100% with a mean of 79.5%. There was preliminary support for the three theoretically proposed predictors of adherence; adherence was slightly higher in RCT studies (compared to observational studies), in studies with higher levels of social support and in studies with higher levels of servicer user involvement.

Conclusion: Adherence to mobile and web-based interventions is robust regardless of service-user (e.g. symptoms severity) and intervention (e.g. type of technological interface) specific factors. Future studies should consider reporting a universal measure of adherence such as percent of adherence and should aim to conduct complex analyses on predictors that may impact on adherence including social presence, service user involvement and the type of study.

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1. Introduction

1.1 Background

The development of appropriate interventions for people with psychosis is challenging as adherence, defined as the extent to which a participant experiences or engages with an intervention (Christensen, Griffiths, & Farrer, 2009), is inconsistent with rates ranging from moderate to low. Of those who have access to interventions, drop out and non-adherence rates are high, around 25% (Leclerc et al.; Nose et al., 2003; Sendt, Tracy, & Bhattacharyya, 2015); non-adherence to programs for people with first episode psychosis (FEP) is estimated to be between 30-57% (Stowkowy, Addington, Liu, Hollowell, & Addington, 2012). These rates are mirrored across both psychological and psychopharmacological interventions.

Research is needed that targets adherence to effective treatments and interventions. Traditionally, poor adherence in people with psychosis has been explained by the presence of debilitating symptoms and the accompanying socio-economic, cognitive and functional impairments (Leclerc, Noto, Bressan, & Brietzke; Nose, Barbui, Gray, & Tansella, 2003). These factors may combine to make illness self-management and engagement with community treatment difficult (Fagiolini & Goracci, 2009; Leucht & Heres, 2006). Although examining service-user, medication or environment related issues may be a helpful first step, the service users' perspective on adherence is rarely consulted. Service users' perspectives are important to consider as some interventions may be more suited to short term use while others may be more acceptable for regular, long term use. Service users provide a valuable voice that can provide direction and improve positive outcomes for the field (Alvarez-Jimenez, Alcazar-Corcoles, González-Blanch, et al., 2014; Eisner, Drake, & Barrowclough, 2013; Reeder et al., 2016; Wykes & Brown, 2016).

Innovative and accessible 'e' mental health interventions, defined as 'the use of information and communication technology to support or improve mental health care' (Ben-Zeev, 2014; van der Krieke, Wunderink, Emerencia, de Jonge, & Sytema, 2014), have

been proposed as an alternative to traditional interventions that could have significant advantages for improving engagement and adherence to treatment for people with psychosis. It has been suggested that mobile and web based interventions may improve access to care, overcome stigma and introduce new models of care that combine mobile and face to face interventions (Alvarez-Jimenez et al., 2012; Ben-Zeev, Kaiser, & Krzos, 2014a; Marzano et al., 2015). Researchers and clinicians have worked together to make use of the recent boom in technology to develop mobile and web-based interventions for a range of mental health disorders including depression, PTSD, panic, stress, insomnia and eating disorders (Griffiths & Christensen, 2007). A review of computer based self-management interventions for people with panic, phobia and OCD found that these interventions led to a reduction in symptoms and improved quality of life (Barlow, Ellard, Hainsworth, Jones, & Fisher, 2005). Historically clinicians and researchers have been hesitant to develop similar interventions for people with serious mental illness such as psychosis. This was because of the chronicity, complexity and risk associated with such disorders along with perceived lack of engagement with health services by this population (Bell, Grech, Maiden, Halligan, & Ellis, 2005; Kersting, A Schlicht, S Kroker, 2009; van der Krieke et al., 2014).

Interestingly this is at odds with the service user perspective. A recent survey by Miller, Stewart, Schrimsher, Peeples, & Buckley, (2015) of 80 inpatient-users and outpatients with schizophrenia found that 56% of individuals used text messaging, 46% had an email account and 27% regularly used internet forums. Additionally, service users agreed that using such technology would help them to access mental health professionals and may help with social interactions. Lal & Malla, (2014) surveyed young adults with first episode psychosis and found that 85% reported that they would engage with a web-based intervention such as the you-tube platform for information on medication or symptoms. Along with these recent studies examining service user perspectives, several systematic reviews have established the acceptability and feasibility of mobile and online interventions for this service-user group (Alvarez-Jimenez, Alcazar-Corcoles, Gonzalez-Blanch, et al., 2014; Naslund, Marsch, McHugo, & Bartels, 2015; van der Krieke L et al.,

2013). Recent developments in technology-based interventions for people with psychosis include; internet-based psychotherapy interventions (see Alvarez-Jimenez et al., 2014 for a review), mobile short-message service or text messaging (e.g. Granholm, Ben-Zeev, Link, Bradshaw, & Holden, 2012), telephone or video two-way conferencing (Mohr et al., 2012) electronic systems that support with decision making, virtual reality programmes (D. Freeman, 2008), and smartphone programmes (Ainsworth, Palmier-Claus, Machin, et al., 2013). Therefore, despite initial hesitations from clinicians and researchers, not only are people with psychosis interested in these interventions and engaged in the technology but there is an increasingly large evidence base to support the feasibility and acceptability of these mobile interventions for this service-user group.

When considering the application of novel mobile and web-based technologies for the design of interventions for people with psychosis the current research may be missing two key points. The first is that adherence to these types of interventions may still be a significant barrier to treatment and the second is that the service user perspective is rarely consulted. A recent review of 12 studies showed that service users varied in their engagement with the technological interventions; some service users showed regular or intermittent use and approximately 25-30% of participants did not engage or dropped out[1] (Alvarez-Jimenez, Alcazar-Corcoles, González-Blanch, et al., 2014). The authors suggested that future studies should report on the proportion of people who engage with the technology and good engagement should be measured more consistently. They also suggested that service-user involvement in the development and implementation of mobile and web-based technologies may be an important bridge between the 'online world' and meaningful recovery.

This systematic review will update the review conducted in 2013 (Alvarez-Jimenez et al., 2014) with the latest data on adherence to novel mobile and web-based interventions developed for people with psychosis.

[1] ***Drop out*** is defined as an individual who does not complete the trial protocol or the trial assessments (Christensen et al., 2009)

1.2 The study of Adherence

To date there have been no systematic reviews specifically exploring and synthesizing levels and predictors of adherence to mobile or web-based interventions for people with psychosis. Alvarez-Jimenez et al., (2014) documented the feasibility and types of interventions but did not specifically examine and compare rates of adherence. Previous systematic reviews have developed methods for examining adherence to mobile or web-based interventions for treatment of depression and anxiety (Christensen et al., 2009; Simco, McCusker, & Sewitch, 2014). Christensen et al., (2009) outlined four main approaches to examining adherence (see table 1 for an overview). The first is to examine factors that contribute to dropout from a trial, for example a comparison of baseline symptomology or demographic factors in participants who stay in the trial and those who drop out. The second is to conduct statistical analysis, including correlational or regression analysis within a trial in order to identify potential predictors of adherence. For example the relationship between various demographic, personality, disease specific, or environmental factors and the level of adherence (e.g. the number of mobile phone entries completed) to the intervention. Specific service user factors (e.g demographics, clinical severity) and intervention factors (e.g. week 1 vs. week 2 of intervention) are most commonly explored. The third is to use questionnaires to retrospectively examine participants' experiences of adherence and perspectives on continued use. The fourth approach is to experimentally manipulate factors within a trial to impact upon adherence; for example to compare different technological interfaces, prescribed frequency of use, or behavioural interventions.

TABLE 1 FOUR APPROACHES TO STUDYING ADHERENCE

Approach	Data Expected
1. Analysis of Drop out data	Comparison of adherent and non-adherent service-user data including demographic, symptom, cognitive or other data; baseline assessment of between group differences
2. Within trials analyses to establish relationship between adherence and various factors	Within study correlational, regression or other analysis of *service-user specific factors* or *intervention specific factors* that may impact on the level of adherence to intervention or technology
3. Post-Trial questionnaire on participants experience	Questionnaire data; qualitative or quantitative feedback on satisfaction, acceptability of trial or intervention with specific questions on usability, helpfulness and continued use
4. Experimental Manipulation of Factors impacting adherence	Comparison of interventions or interfaces that are specifically designed to impact on adherence

Terms in this area often have many different definitions and the ones used in this review are based on previous reviews (e.g. Alvarez-Jimenez et al., 2014; Simco et al., 2014) so that it is possible to compare the results. ***Internet/online interventions*** are web-based interventions enabling peer to peer contact, service-user to expert communication or interactive psycho-education or psychotherapy. ***Mobile based interventions*** are defined as interventions delivered via mobile phones using SMS, MSS mobile or web applications. ***Adherence*** is defined as the extent to which a participant experiences or engages with a mobile or internet based intervention (Christensen et al., 2009). Two types of adherence will be investigated; 1) mean percentage of the intervention completed 2) per cent of participants that complete the intervention (Simco et al., 2014). As mentioned previously, ***drop out*** is defined as non-completion of the trial protocol or the trial assessments (Christensen et al., 2009). ***Entry*** refers to data on the frequency and use of an intervention; this could include completion of a mobile phone questionnaire or log-in to a website.

1.3 New Potential Predictors of Adherence

In addition to the four approaches to studying adherence in Table 1, this study will briefly evaluate three theoretically proposed predictors of adherence that have been suggested in recent literature and reviews; (1) level of social presence/contact, (2) servicer user involvement in the development of the intervention and (3) type of trial (highly supported RCT intervention or observational study with limited support from the research team). These three predictors have been proposed as providing key insight into the barriers or bridges to adherence (Alvarez-Jimenez, Alcazar-Corcoles, González-Blanch, et al., 2014; Christensen et al., 2009; Mohr et al., 2011; Wykes & Brown, 2016). In line with Alvarez-Jimenez et al.,'s (2014) recommendation to involve service users, each of these predictors specifically relates to the experience of the service user. These have not been systematically reported or explored in previous reviews. Each potential predictor is discussed in detail below.

The first potential predictor of adherence is the level of social presence/contact. This refers to the frequency and quality of clinician, researcher or peer presence or contact throughout the intervention (Alvarez-Jimenez et al., 2013). Several studies have identified contact and support from clinicians or peers in the form of telephone, email, online forums or e-chats can help improve adherence to mobile and internet based interventions (Mohr et al., 2010; Tate, Jackvony, & Wing, 2006). Mohr, Cuijpers, & Lehman, (2011) suggested a model, 'supportive accountability' whereby supportive social presence may positively influence accountability, expectations, and bond during a mobile or web-based intervention. This predictor has some credibility as Day et al., (2005) found that for acute inpatients with psychosis, a positive relationship with a clinician was related to adherence to medication and positive attitude towards treatment. In addition, Leclerc et al., (2015) established that a good therapeutic alliance improved adherence to psychosocial treatment. The idea of 'supportive accountability' is similar to the well-researched and effective guided self-help programmes that have been developed for mental health disorders such as anxiety and depression (see systematic reviews by (Cuijpers, Donker, van

Straten, Li, & Andersson, 2010; Van't Hof, Cuijpers, & Stein, 2009). In the guided self-help model there is usually a coach, therapist, or clinician who can actively guide clients through the intervention protocol and potentially monitor treatment response (Cuijpers et al., 2010; Seekles, van Straten, Beekman, van Marwijk, & Cuijpers, 2011). Cuijpers (2011) defines guided self help as 'support given by the therapist (that) should primarily be of supportive or facilitative nature, and is meant to support the patient in working through the standardized psychological treatment'. Although this overlaps with the model of supportive accountability, in this study we seek to explore, how different, potentially less formal levels and methods of support embedded or alongside technology, might affect adherence for people with psychosis. In order to profile the characteristics of effective online or mobile interventions this review will conduct a preliminary examination of the level of social presence and human support that is offered in each intervention.

The second potential predictor of adherence is the level of service user involvement in the development of the intervention and providing feedback. This has been highlighted as vital for effectiveness and adherence to interventions (Alvarez-Jimenez et al., 2014; Wykes and Brown, 2016). The sense of involvement in the project may promote self-efficacy and therefore accountability to the intervention (Mohr et al, 2011). Recently, Wykes and Brown (2016) emphasized the importance of providing service users with choice, for example the choice of digital or face-to-face intervention. Choice leads to a greater feeling of control; this may tap into intrinsic motivation that is important for adherence to interventions (Mohr et al., 2011). This review will highlight any studies that involve service users in the development and improvement of the interventions and the potential impact on adherence.

The third potential predictor of adherence is study type. Levels of adherence may be different if the service user is actively participating in a clinical trial that is specifically testing an intervention (i.e. RCT), or if they are using open access, self-directed technology that is not associated with a clinical trial. Trials of web based interventions show high levels of adherence while observational studies of open access websites often reveal poor

adherence and dropouts (Christensen et al., 2009). This may be because of differences in incentives (e.g. payment for participation) or because there is often more research and clinician support associated with clinical trials. It will be important to design technologies and programmes that will maintain high adherence outside of the context of a clinical trial (Christensen et al., 2009).

1.4 Aim of review

As this review is an update of a previous review (Alvarez-Jimenez et al., 2014) we have chosen a narrow time frame and to replicate the narrow search criteria of the previous review. We sought to do this for four main reasons:

1) Due to the rapid proliferation of publications in this field in the last 5 years (over 2000 OVID search hits), we sought provide a narrow focus to make the data more concise and accessible to readers who wish to be up to date (Higgins and Green, 2011, Cochrane Handbook for Systematic Reviews of Interventions). Additionally an update of a review should occur every two years, especially in a rapidly growing field (ibid).

2) We sought to build on the findings from the Alvarez-Jimenez et al., (2014) review and examine adherence across the most recent studies and technological developments. The original study documented levels of adherence and we sought to expand on this and examine how this has developed in the last 2 years. Using these search terms we were able to include 17 new and relevant papers.

3) We expanded slightly on the narrow search terms used by Alvarez-Jimenez et al., (2014) to include 'bipolar disorder or manic depression or manic depressive illness or manic-depressive psychosis' with the aim of capturing the recent developments for these patient groups, and in particular, any overlap with schizophrenia spectrum disorders.

4) We chose to update the Alvarez-Jimenez et al., 2014 review because one of the main findings from the previous review was that mobile and online interventions may improve socialization and social connectedness. We therefore conducted a specific analysis of

social factors (e.g. the social presence analysis). We sought to provide an overview of this potential predictor in order to introduce readers to this potentially important new area.

Along with reporting and synthesizing data according to the four approaches to studying adherence mentioned in Table 1 ((1) Analysis of Drop out data (2) Within trials Analyses to establish relationship between adherence and various factors (3) Post-Trial questionnaire on participants experience (4) Experimental Manipulation of Factors impacting adherence) this review will also provide a brief preliminary examination and overview of potential predictors of adherence including; level social presence across trials, service user involvement and the type of study (RCT or observational).

2. Method

This systematic review was conducted following the PRISMA guidelines and recommendations for conducting and reporting systematic reviews (Preferred Reporting Items for Systematic Reviews and Meta-analyses, PRISMA, Moher, Liberati, Tetzlaff, & Altman, 2010). The criteria are listed in the Appendix 4 with page numbers for where compliance is noted in the text.

2.1 Search Strategy

The following databases were systematically searched from August 2013 until May 2015: OVID including MedLine, EMBASE and PsychInfo, Pubmed and Web of Science. The following terms were used in the keyword search of abstracts and titles (internet or online or web-based or website or mobile) AND (bipolar disorder or manic depression or manic depressive illness or manic-depressive psychosis or psychosis or schizophr* or psychotic). Additionally, hand-searching was performed on five key journals (*Schizophrenia Bulletin*, *Schizophrenia Research*, *Journal of Medical Internet research*, *Telemedicine and e-health*, *Psychiatric Services*) along with the reference lists of included primary studies. The term 'adherence' was purposely not included in the search terms as this would significantly

limit the number of included studies. Most studies do not include references to reported adherence in the title or abstract (Simco et al., 2014).

2.2 Eligibility criteria

Studies that were considered for inclusion in this systematic review including the following PICOS criteria (Higgins & Green, 2011): (1) ***Population***: Adults (18-65 years); at least 75% of participants have a diagnosis of schizophrenia spectrum disorder according to DSM-IV or ICD-10. (2) ***Interventions, trials or observational studies involving***: online, mobile, e-technology or web-based interfaces enabling peer-to-peer contact, patient-to-expert communication or interactive psycho education/therapy; flexible, accessible monitoring, self-help, symptom management, (3) ***Study design***: As this study aims to provide an overview of the current state of the field, generous inclusion criteria for type of study were adopted. Types of studies: (i) All types of primary group studies including randomised controlled trials, cross-sectional, longitudinal as well as comparison studies with and without a control group, cross-over trials, case controls or cohort studies, observational studies, feasibility or acceptability studies. (ii) English language (4) ***Outcomes***: At least one measure of adherence. The following exclusion criteria were used; conference abstracts and theses not published in a peer-reviewed journal (see Appendix 1 Form A for inclusion criteria of studies).

Titles and abstracts of articles were scanned independently by two researchers (CK and ZH). Articles deemed potentially eligible were retrieved in full and independently reviewed (CK and ZH) using a standard form listing inclusion criteria (Form A Appendix 1). Disagreement between researchers was dealt with by consensus with a senior member of the research team (TW).

2.3 Data extraction and analysis

A standard form was used to extract data from selected studies to create two results tables (please see Appendix 2 for tables 2 and 3). Tables 2 and 3 are composed of three sections; a) Randomized Intervention studies, b) Feasibility or Acceptability studies, c)

Observational studies. Table 2 includes the following study characteristics; (i) study source, sample size, gender, age, diagnosis, study design (ii) purpose of intervention, (iii) control group. Table 3 includes characteristics of interventions: levels of adherence, dropout, type of social presence, service user involvement and measurement of participant feedback. The above data were extracted independently by two researchers (CK and ZH). Any discrepancies were identified and investigated by referral back to the original article by consensus of the research team.

2.4 Assessment of methodological quality and procedures

The Clinical Trials Assessment Measure (CTAM) (Tarrier & Wykes, 2004) was designed to assess trial quality specifically in trials of psychological interventions for mental health. It contains fifteen items grouped into six areas that are important for assessing bias in psychological interventions including; sample size, recruitment method, allocation to treatment, assessment of outcome, control groups, description of treatments and analysis. Each study is rated out of a total of 100. This scale has good inter-rater reliability (.96) and high concurrent validity (=.97). Eleven of the studies were considered to be intervention based studies or randomized controlled trials and were assessed using this measure. Six trials were assessed using the Downs and Black scale (1998) for non-randomized controlled trials or observational studies. This scale consists of 27 questions assessing key areas of methodological quality for non-randomized trials for systematic reviews. It includes questions on reporting, external validity, bias, confounding and power. This scale was modified slightly for the current study. The question on power (27) was simplified to a rating of 1 or 0 which has been done in other reviews (van der Krieke et al., 2014; Samoocha, Bruinvels, Elbers, Anema, & van der Beek, 2010). Each study is rated out of a total of 28 points. Scores are classified in the following ranges; excellent score 26-28, good score 20-25, fair score 15-19 and poor less than 15. Two reviewers (CK and ZH) independently assessed the trial quality for all of the included studies. All of the first authors of the included articles were contacted to approve that CTAM or Downs and Black rating for the article and if necessary provide further information about the study. This

was to ensure that the quality of the trial was not confused with the quality of the reporting in the study.

3. Results

The included studies were heterogeneous in terms of intervention and measurement of results; hence we report a narrative synthesis of the findings. Information on study selection and study characteristics is followed by a synthesis of data on each of the four approaches to measuring adherence. Finally, data and information on the three potential new predictors of adherence is presented.

3.1 Study Selection

The search strategy returned 2627 titles and abstracts. After removal of 797 duplicates, 1830 titles and abstracts were screened and 96 full text papers were assessed for inclusion. 17 studies met the inclusion criteria (see summary in Figure 1 PRISMA Flow chart).

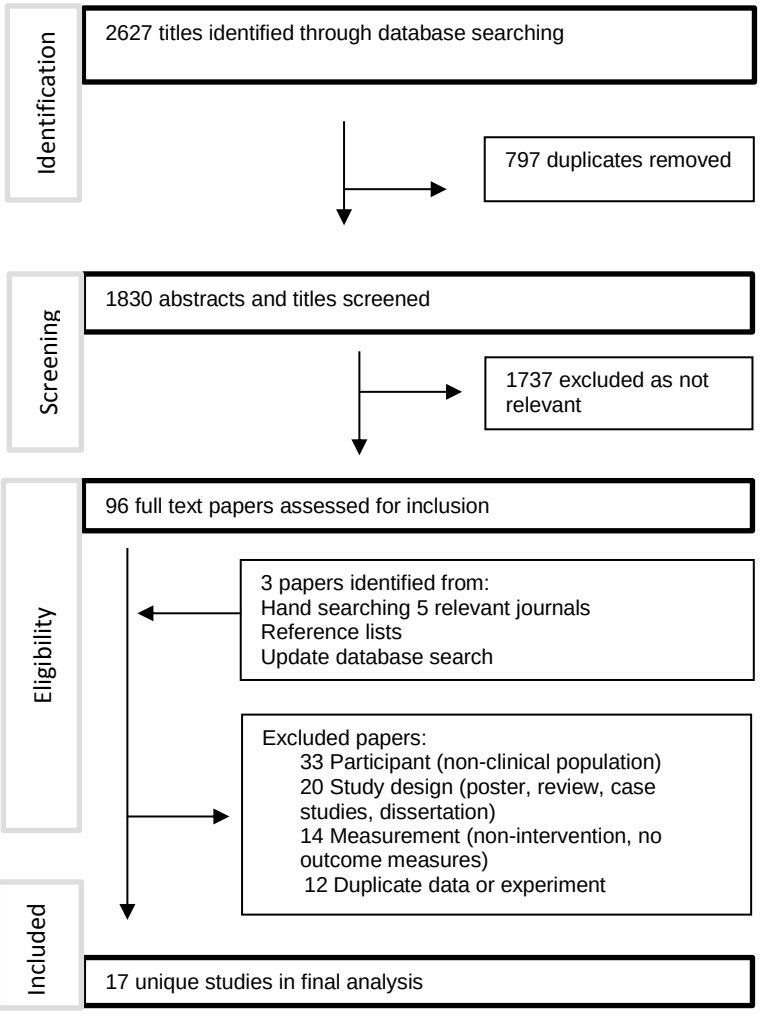

FIGURE 1 PRISMA FLOW CHART

3.2 Study Characteristics

Study characteristics are summarized in Table 2 (Appendix 2). Five were randomized controlled interventions[2], six were feasibility, acceptability studies and six were observational studies. In total, 558 participants with a diagnosis of schizophrenia spectrum disorders and a mean age ranging from 20 to 48 years participated in the 17 studies. 13 studies included individuals with schizophrenia or schizo-affective disorder, one study

[2] For clarity, randomized controlled trials are defined as trials with a randomized control group and pre and post outcome measures; Feasibility or acceptability studies are defined as studies that assess the usability, feasibility, and acceptability of an intervention and may have a case control group or single group design; Observational studies are studies where the researcher observes and records behaviour in a systematic way without manipulating variables, e.g. experience sampling methods (Yang et al., 2010).

included individuals with first episode psychosis, one study included individuals with a dual diagnosis of schizophrenia and substance misuse and two studies included individuals with non-affective psychosis.

Tables 3 summarizes the characteristics of the interventions and studies. There was heterogeneity in the design and aim of the interventions. Of the mobile based trials six used momentary experience sampling methods to measure mood (Brenner & Ben-Zeev, 2014; Kimhy et al., 2014a) or symptoms (Hartley, Haddock, & Vasconcelos e Sa, 2014; Kimhy, Vakhrusheva, Liu, et al., 2014b; Kimhy, Vakhrusheva, Khan, et al., 2014a; Sanchez, Lavaysse, Starr, & Gard, 2014; So et al., 2013). Two mobile phone interventions involved personalized text messages or phone calls from a researcher or clinician (Beebe, Smith, & Phillips, 2014; Dror Ben-Zeev, Kaiser, & Krzos, 2014) and one involved an online mobile interface for psychoeducation (Ben-Zeev, et al., 2014). Of the web-based interventions two involved modules of psychoeducation (Gleeson et al., 2014; van der Krieke L et al., 2013) and four involved an element of online psychosocial training (Kurtz, Mueser, Thime, Corbera, & Wexler, 2015; Nahum et al., 2014; Smith et al., 2015; Ventura, Wilson, Wood, & Hellemann, 2013).

3.2.1 Quality Assessment

Trial quality results are presented in Appendix 3 for the eleven RCT/feasibility and the six non-randomized studies respectively. All of the primary authors of the included studies were consulted and confirmed the quality ratings provided in Appendix 3.

The RCT studies (n=5) and feasibility or acceptability studies (n=6) were rated using the CTAM. In terms of the RCT studies and feasibility studies, the average trial quality score on the CTAM was 57.54 and ranged from 36-88. Evidently the feasibility trials had a lower average rating (41.8) than the RCT trials (76.4). These studies would have received a lower quality rating because the design did not include control groups or large sample sizes (see studies: Nahum et al., 2014; Gleeson et al., 2014; Ben-Zeev et al., 2014a, Ben-Zeev et al., 2014b, Ventura, 2013, Palmier-Claus, Ainsworth, & Machin, 2013a). There was variability in the methodological quality of the RCT and feasibility trials. For example, only

four of the studies had outcome assessments conducted by assessors blinded to group. All of the studies had interventions carried out by independent assessors, (not therapists or clinicians), and had adequate handling and assessment of dropouts if dropout exceeded 15%. All of the RCT studies were deemed to be of adequate trial quality (rating of 65+, Wykes, Steel, Everitt, & Tarrier, 2008), except for Palmier-Claus et al., 2013b which received a rating of 62.

The mean quality rating for the non-randomized studies was 20.3 and ranged from 17 to 24. Three studies fell into the 'good' classification range and three fell into the 'fair' classification range. This is in line with previous reviews (van der Krieke et al., 2014). Only two of the studies provided information on the power analysis. The questions on randomization were included and scored to keep consistency but in every case they did not apply as these were not designed as randomized controlled trials.

3.3 Adherence: Types of Measurement across studies

The most common measures of adherence were percent of intervention completed by participants and percentage of participants completing the intervention. Figure 2 displays the types of adherence measure used and the level of adherence for each study. For the five studies reporting the percentage of participants completing the intervention, adherence ranged from 60% to 100% with a mean of 79.5%. For the 12 studies reporting mean% of the intervention completed by participants' adherence ranged from 59-98% with an average of 60.46%. All of the studies also listed the number of participants that dropped out of the trial. This ranged from 0-37% with a mean of 12.42% drop out across both observational and intervention studies.

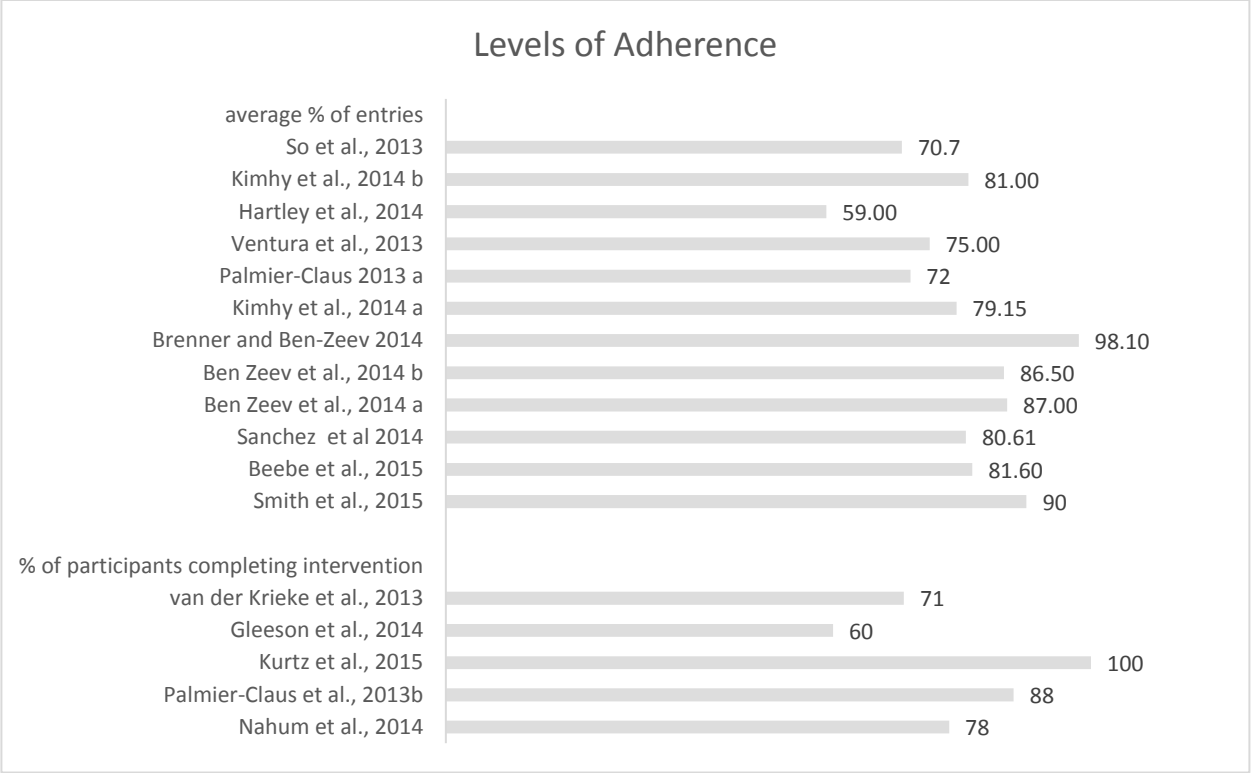

FIGURE 2 ADHERENCE ACROSS ALL STUDIES; AVERAGE PERCENT OF ENTRIES COMPLETED IN EACH STUDY FOLLOWED BY PERCENTAGE OF PARTICIPANTS COMPLETING THE INTERVENTION.

Some studies also analyzed factors that may predict adherence. Five of the 17 studies analyzed the data of individuals who dropped out of the study before the completion of the trial, to determine any differences in symptoms or service-user demographics between the adherent and non-adherent groups. Five studies analyzed specific predictors of adherence; these could include person-specific predictors (disease severity, age, and gender) or intervention-specific (type of technology, duration of intervention). Eight of the studies also included a post-trial questionnaire of participants' perceptions and experiences of the intervention, ease of use, acceptability of the trial and overall satisfaction. Two studies conducted an experimental manipulation to potentially affect adherence. Additionally, two studies found that adherence to the trial had an impact on the intervention outcomes. The specific findings for each of these four approaches to studying adherence will be discussed in the following sections.

3.3.1 Approach 1: Analysis of dropout

Five studies analyzed the relationship between specific variables and dropout. The studies produced different results depending on which variables were investigated and which analysis was adopted. Van der Krieke et al., (2013) found that the drop-outs tended to be younger and male although Palmier-Claus et al., (2013a), using logistic regression, found that higher severity on the PANSS positive symptom subscale (but not age or gender) predicted nonadherence with the trial. Sanchez et al., (2014) found no cognitive functioning data related to people who completed the study. Finally, Hartley et al., (2014) and So et al., (2013), who investigated an inclusive set of variables (age, symptoms, severity of delusions, education or gender), found no differences between those who completed the trial and those who did not.

3.3.2 Approach 2: Analysis of within trial predictors of adherence

Very few studies (n=5) conducted analyses within the trial to examine predictors of adherence. The types of analysis completed included Pearson product-moment correlations, one-way ANOVA's and multiple regression analyses. In terms of service-user specific factors, Van der Krieke et al., (2013) analyzed the chronicity of symptoms and reported that service-users with first episode psychosis used a web-based decision aid autonomously more often than service-users with chronic psychosis. For example, they used their own computer and used the web programme without assistance from the research team more often. They also found that 56% of the participants who completed the intervention were service-users in long-term care. However, the report does not provide specific statistical data.

Ben-Zeev et al., (2014b) found no relationship between baseline cognitive functioning, negative symptoms (PANSS negative symptom subscale), persecutory ideation (suspiciousness item from PANSS) and the use of the FOCUS mobile intervention (days used, number of times used per day). Palmier-Claus et al., (2013a) also found no relationship between age, gender, PANSS subscales and Calgary Depression Scales and the total number of entries completed by each individual. They also examined symptom

severity and compared three groups of individuals with acute, remitted and ultra-high risk of psychosis and found no significant differences between the groups. Finally, Kimhy et al., (2014a) conducted a correlation analysis to examine associations between ratings of emotions and number of experience sampling method (ESM) responses. They found no significant associations.

In terms of intervention specific issues, Palmier-Claus et al., (2013b) found no relationship between the length of time taken to complete an entry significantly and the number of entries completed by an individual. They also examined number of entries completed across the number of weeks of the study. They found that more entries were completed in the first week than the second week of the intervention and participants rated more highly the question 'were there times when you felt like not answering?' during the second week.

In summary, in terms of predictors of drop out or adherence, few studies (n=10) conducted analysis and those who did revealed limited findings. In terms of service user specific factors, one study found that PANSS positive symptoms predicted non-adherence, another found that people with first episode psychosis used the intervention independently. For intervention specific factors, one study found that more entries were completed during week 1 of an intervention.

3.3.3 Approach 3: Post-Trial questionnaires on participants perspective on adherence

Eight studies retrospectively asked participants to provide questionnaire-based qualitative or quantitative feedback about their experience of the trial or intervention. All the studies used different rating scales (e.g. Treatment Experience Questionnaire in Smith et al., 2015; idiosyncratic quantitative feedback questionnaire in Palmier-Claus et al., 2013b; idiosyncratic SocialVille programme rating in Nahum et al., 2014) so it is difficult to draw comparisons across studies. Only four studies specifically asked if participants would continue to use the intervention (Nahum et al., 2014; Gleeson et al., 2014; Smith et al., 2015; Palmier-Claus et al., 2013b; see figure 3). For three studies the mean percent of

participants who agreed to continue to use the intervention was 74.8%. The fourth study, Palmier-Claus et al., (2013b), asked participants to indicate for how long they would be willing to use the smartphone or text message intervention. The majority of participants (42%) indicated that they would be willing to complete either the mobile or text-based intervention for 2-3 weeks. Ratings of 'continued use' could be a helpful measure of current and future adherence given that the interventions may help with maintenance treatment. Another important factor to consider is the problem of assessing satisfaction and use of a trial non-independently. It is commonly found that satisfaction ratings are raised when questionnaires are administered by members of the trial. In the future, independent data collection, perhaps from service user researchers not associated with the trial may provide a more unbiased and critical view of the interventions.

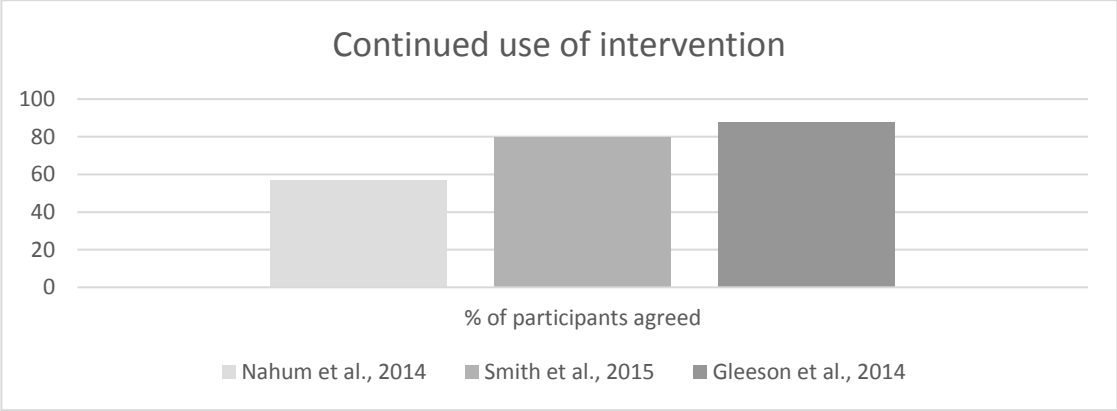

FIGURE 3 PERCENT OF PARTICIPANTS AGREED TO CONTINUED USE OF INTERVENTION; THIS EXCLUDES THE PALMIER-CLAUS ET AL., 2013B RATING AS IT MEASURES FOR HOW LONG THE INTERVENTION WOULD BE CONTINUED.

3.3.4 Approach 4: Analysis of specific intervention manipulations and effect on adherence

Two interventions were designed to manipulate conditions that may have an impact on adherence. Palmier-Claus et al., (2013b) compared two different types of interventions; SMS text-only interface or a smartphone graphical application. They assessed the acceptability and feasibility of each device and found that participants completed more data points when using the smartphone interface (average entries=16.5) compared with the SMS text only interface (average entries= 13.5; p=.002); and most participants

preferred the smartphone application (67%) and found it easier to use (71%) although this difference was not statistically significantly different.

Beebe et al., (2014) examined the impact of telephone interview, text message or both interventions to assist with medication adherence. They found that mean psychiatric medication adherence scores were highest for the telephone interview plus text messaging group compared to the telephone interview only group (by an average of 5.3%) and the text only group (by an average of 13%). Although this result is related to medication adherence, not adherence to the mobile intervention, it is an interesting example of how the design of the study (text message vs. telephone interview) can be manipulated to impact on clinical outcomes (e.g. medication adherence).

Interestingly two interventions found that adherence significantly affected the intervention efficacy. Smith et al., (2015) found that completing more training trials of a virtual reality job interview training correlated with fewer weeks searching before securing a job ($p<0.001$) and greater self-confidence ($p=0.03$).

Ben-Zeev et al., (2014b) analyzed symptom change throughout the intervention and any related association to adherence. They conducted Pearson correlations of change on the Beck Depression Inventory (BDI) and PANSS scores along with the percent of days participants used the mobile intervention and found that change in participants' BDI scores was significantly correlated with use of mobile intervention; the less frequently that participants used the FOCUS mobile intervention the greater the reduction in depression score. Change in PANSS scores was not associated with use of the FOCUS app.

In summary, the four approaches to studying adherence (1) Analysis of Drop out data (2) Within trials analyses to establish relationship between adherence and service user or intervention factors (3) Post-Trial questionnaire on participants experience (4) Experimental Manipulation of Factors impacting adherence, provided an overview of how adherence is measured across mobile and internet interventions for people with psychosis. Drop out ranged from 0-37% with an average of 12.42% across both observational and intervention studies. The percentage of participants adhering to

interventions ranged from 60% to 100% with a mean of 79.5%. Less than 50% of trials (29% 5/17) further explored specific factors or predictors of adherence, but those who did found limited associations between baseline clinical or demographic factors and adherence. Post-trial questionnaires in four studies found that 74.8% of participants agreed to continued use of the intervention. Finally, 11% of studies conducted an experimental manipulation to investigate the effects on adherence, for example, manipulating the mobile interface (either text message or smartphone) and found that smartphone interventions were preferred by service users.

3.4 New Potential Predictors of adherence

Along with synthesizing the information from studies reporting on the four methods of analyzing adherence above, this review also provides a brief original exploration of three potential predictors of adherence; level of social presence, level of service user involvement and type of study.

3.4.1 Potential Predictor: Social Presence Analysis

In order to assess Mohr et al's (2011) theory that increased social presence will lead to better adherence we examined the amount of contact for each trial and the level of adherence to the intervention. As there is heterogeneity across the trials we provide a narrative synthesis. Across all 17 studies the mean number of contacts per week from a researcher or clinician was 4.8 and it ranged from 0 to 28 contacts per week. This included face-to-face, mobile, web-based or telephone based contacts. As expected, the highest number of contacts was in the clinician- or researcher-led mobile interventions, with a mean of 19 contacts per week. The highest number of contacts across all studies was the mobile intervention by Sanchez et al. (2014), where participants were interviewed over the phone about their environment, goals, and activities four times a day resulting in 28 contacts a week. The lowest was in the ESM based studies with an average of one contact per week. Psychoeducation web-based studies had a mean of 3.6 contacts/week and training studies had a mean of 1.75 contacts per week.

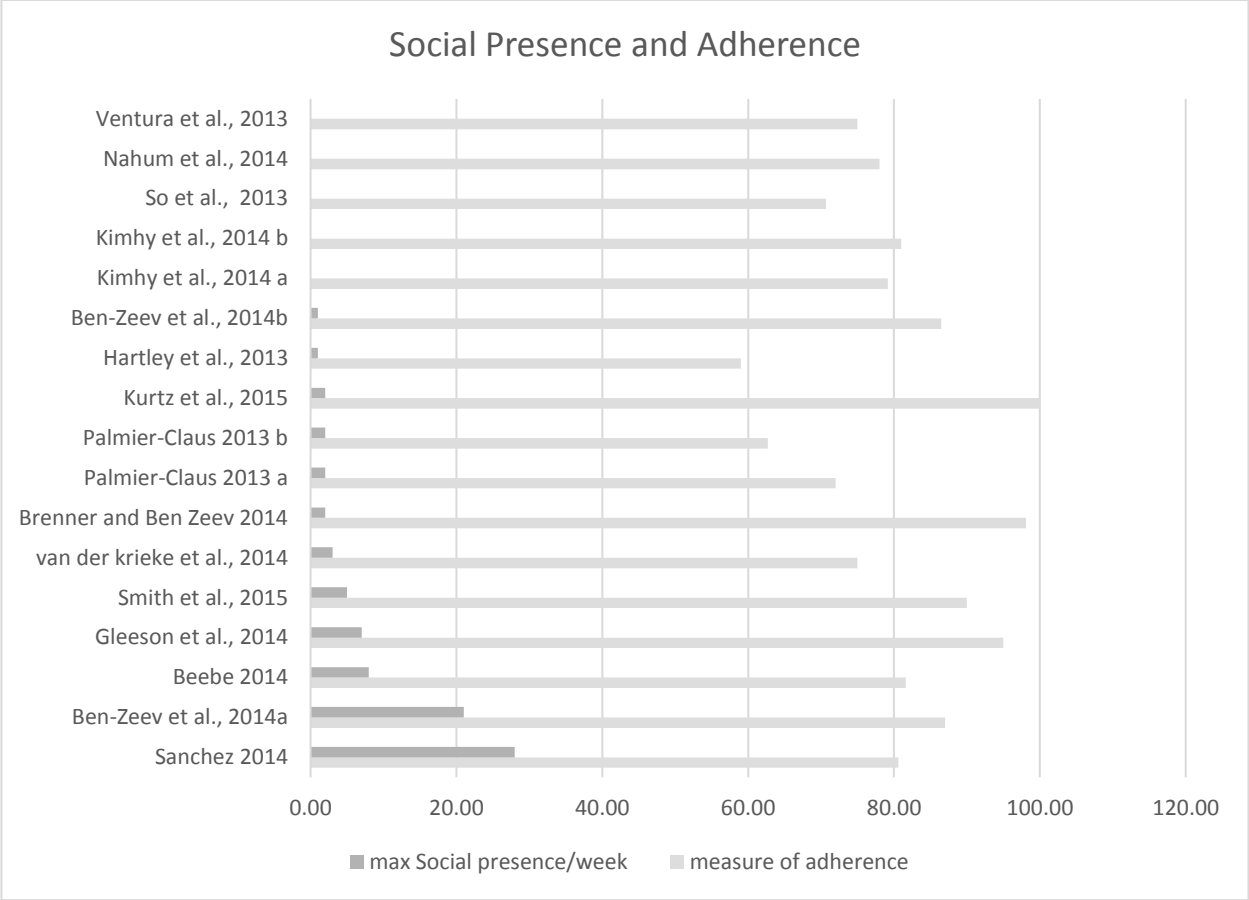

FIGURE 4 SOCIAL PRESENCE (E.G. MAXIMUM INSTANCES OF POTENTIAL RESEARCHER OR CLINICIAN CONTACT PER WEEK) AND ADHERENCE (E.G. % OF PARTICIPANTS COMPLETING THE INTERVENTION), ORDERED FROM LOWEST AMOUNT OF SOCIAL PRESENCE TO HIGHEST AMOUNT

Overall the amount of social presence varied between the different interventions. Interestingly in interventions where there was little or no contact with researchers or clinicians, such as the ESM-based interventions, there was still a high adherence rate with a mean of 74.6%; ranging from 59% to 98.1%. However, the adherence rates for ESM-based interventions (74.6%) were on average 10% lower than for the other types of interventions; clinician/researcher led mobile interventions had a mean adherence rating of 83%, web-based psychoeducation interventions had a mean adherence rating of 85.5% and web-based training studies had a mean adherence rating of 85.7%.

Anecdotally the importance of social presence is confirmed from participant reports. Gleeson et al., (2014) found that 90% of participants cited the use of an online facilitator

contributed to their sense of safety when using the online programme. All participants either agreed or strongly agreed with statements such as they always felt supported by the online facilitator and 60% reported an increase in feelings of social connectedness. Ben-Zeev et al., (2014a) examined therapeutic alliance and found that participants rated the relationship with the mobile interventionist significantly higher (more positive) than for their community-based clinicians. Based in these preliminary findings it will be useful for future studies to explore the relationship between social presence and adherence.

3.4.2 Potential Predictor: Service user involvement

The second potential predictor is the level of service user involvement in the development and feedback on the intervention. Of the 17 studies included, only two studies described service user involvement in terms of the development or initial piloting of the intervention. Six studies also included retrospective questionnaires about participant experience however participants were not specifically consulted about the development of the current intervention.

Co-production, meaning the collaboration of service users and researchers, in the beginning phases of intervention development has a potential influence on participants' perception and adherence to the intervention. Ben-Zeev et al., (2014b) used feedback and recommendations from a pilot with service users to develop a mobile intervention, FOCUS, to facilitate real-time mobile illness self-management. They found that participants rated the intervention highly with 90% acceptability and the average percent of entries completed was 86.5%. Gleeson et al's (2014) HORYZONs programme was developed with a service user focus group. It was found that 95% of participants used the social media component, 60% completed the therapy modules and 75% reported a positive experience with the program. It would appear that the interventions that are developed with service users in focus groups or interviews had high ratings of adherence and satisfaction ratings (Ben-Zeev 2014b; Gleeson et al., 2014), however, this should be investigated further.

3.4.3 Potential Predictor: Type of Study and Level of Adherence

Of the 17 studies included, twelve were feasibility, acceptability or observational studies and five were RCTs. In the five RCTs the reported adherence level for the percent of participants completing the trial (N=3 studies) was 86.3% and mean % of entries completed was 85.8 (N=2 studies). In the observational or feasibility studies only one study reported the percent of participants completing the trial, which was 60%. The remaining 11 observational or feasibility studies reported the mean number of entries completed as 78.82%. Evidently there are no large difference between RCTs and observational/feasibility studies in terms of reported levels of adherence, however, adherence to RCT's was slightly higher by approximately 8%.

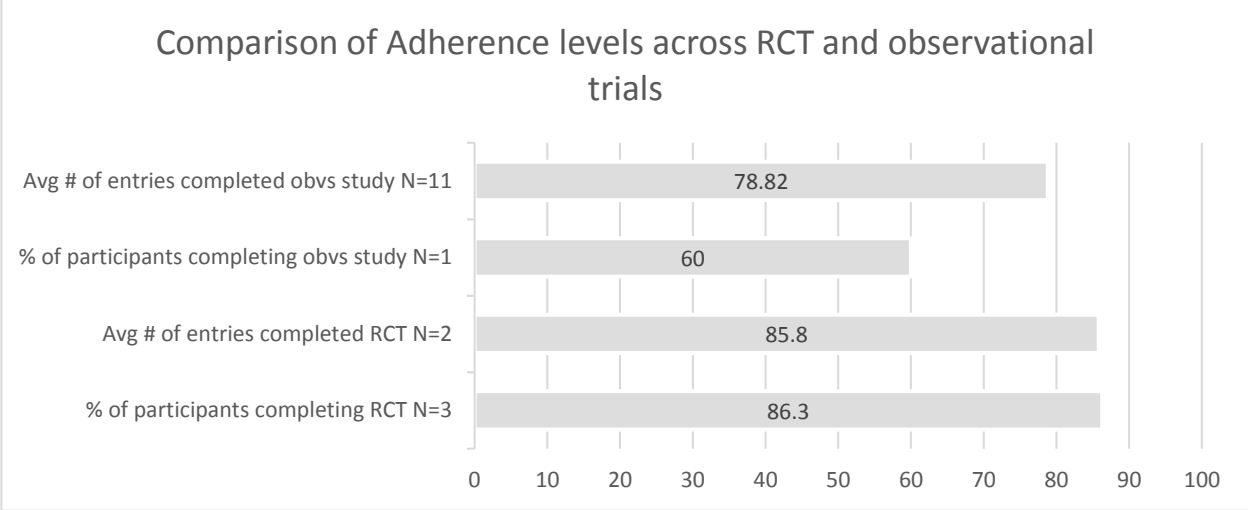

FIGURE 5 COMPARISON OF REPORTED ADHERENCE FOR RCT AND OBSERVATIONAL STUDIES COMPARISON OF REPORTED ADHERENCE FOR RCT AND OBSERVATIONAL STUDIES. THE BAR CHART IS DIVIDED INTO FOUR SECTIONS: % OF PARTICIPANTS COMPLETING THE INTERVENTION OR AVERAGE NUMBER OF ENTRIES FOR RCTS OR NON-RCTS/OBSERVATIONS STUDIES SEPARATELY. N IS THE NUMBER OF STUDIES IN THIS CATEGORY

4. Discussion

This review provides an overview of rates and measurement of adherence to web-based or mobile interventions or trials for individuals with psychosis. The studies varied in terms of the types of adherence measurement used, within-trial predictors that are associated with adherence, questionnaires used to assess participants' perspectives on factors impacting adherence, and any experimental manipulations conducted to impact on adherence. Despite previous reviews of the acceptability and types of interventions (e.g. Alvarez-Jimenez et al., 2014), this is the first review to document rates of adherence and to explore predictors of adherence to mobile and web-based interventions or trials for people with psychosis. Although all of the studies reported either the percent of individuals completing the intervention or the average percentage of entries completed in the intervention, only 29% analysed specific predictors of drop-out, 23% examined person-specific or intervention-specific predictors of adherence, 23% assessed participants' perspectives on continued use of the intervention, and 11% conducted an experimental manipulation to investigate the effects on adherence. The brief review of the theoretically proposed predictors of adherence in terms of level of support, involvement and trial type confirmed these factors are important areas of future investigation as discussed below.

4.1 The Measurement of Adherence

In terms of reported levels of adherence to mobile or web-based interventions, this review finds that adherence rates to mobile and web-based interventions for people with psychosis are in line with adherence rates for similar technology-based interventions for other mental health disorders. In the current review, for the five studies using the measure of the 'percentage of participants completing the intervention', adherence ranged from 60% to 100% with a mean of 79.5%. For the 12 studies reporting 'mean % of the intervention completed by participants' adherence ranged from 59-98% with a mean

of 60.46%[3]. In line with the current adherence rates, Simco et al., (2014) found that the mean per cent of individuals completing self-care interventions (including computer or web-based) for depression or anxiety was 66%. A systematic review of computerized CBT intervention for depression and anxiety found that only a median of 56% of participants completed the online interventions (Waller & Gilbody, 2009). Christensen et al., (2009) found that for participants with depression, completion of an online treatment ranged between 50-70% whereas rates for completion of an online site for Personality Disorder ranged from 80-100% completion; social phobia reported 70-90% completion and the only PTSD intervention reported completing rate of 64%. Overall the current review finds similar, if not higher, levels of adherence to web-based or mobile interventions for psychosis.

In terms of adherence across different types of interventions for psychosis (e.g. face to face; medication based interventions) this study finds that reported rates of adherence for web-based or online interventions are in line with face-to-face interventions. Startup, Jackson, & Startup, (2006) found that completion rates of a one-to-one CBT intervention for psychosis was 55%. Similarly, Alvarez-Jimenez et al., (2009) found that the completion rate for a one-to-one CBT intervention for first episode psychosis (FEP) was 68.3%. Overall adherence to web-based and mobile interventions for people with psychosis may be higher than face-to-face interventions, with rates of 79.5%.

4.2 Quality of studies

As might be expected the RCT studies were rated more highly (76.4%) than feasibility trials (41.8%). This is consistent with the characteristics of the CTAM quality measure as it is most suitable for RCTs. All of the RCT studies were rated above 65, except one (Palmier-Claus et al., 2013b), which is deemed to indicate that the trial quality is adequate (Wykes, 2008). In the future, for RCTs, an analysis that compares the effect size of interventions

[3] Table 3 notes the different criteria or thresholds that studies may have used to determine 'completion' or 'compliance' rates for the study or intervention

and trial quality would help to clarify the effectiveness of mobile or web-based interventions. In terms of observational studies these studies were classified as either fair or good trial quality. Few trials (n=4) used a method of blind rating of outcomes. This is particularly important when assessing service user satisfaction with the intervention, as researcher involvement may unintentionally bias the ratings of service users.

4.3 Predictors of adherence

Specific Predictors: Service User or Intervention Factors

The current review found only four studies that examined specific predictors of adherence. Younger age, and less chronic symptoms were significant (van der Krieke et al., 2013) and a higher rate of adherence was found in the first intervention week than the second (Palmier-Claus et al., 2013b). Although other predictors of adherence were examined (cognition, negative symptoms, persecutory delusions) none were found to have a significant effect.

Complex analyses, such as the multiple regression analysis performed by Palmier-Claus et al., (2013a), of specific predictors such as service-user factors (symptoms, socio-economic factors, interpersonal factors, cognitive factors) along with e-mental health intervention factors (complexity of the interface, cost, and access) should be a priority for future studies. This will inform which service-user group may benefit from different type of interventions.

New Predictors of Adherence

Although specific predictors of adherence were not commonly analyzed and few were found to be significant, the proposed theoretical predictors of adherence proved useful areas to examine in the future. Recently Mohr et al., (2011) proposed that web-based and mobile interventions for e-health could benefit from alignment with a new theoretical model of adherence; 'supportive accountability'. They argue that adherence can be improved by including a level of human contact or support along with accountability to another person e.g. a coach, moderator or therapist. They outline how this model is

moderated by reciprocity in the relationship, motivation of the service-user, and the communication interface (e.g. computer or mobile). "Support" in this review was defined liberally as any type of contact with a clinician or researcher involved in the trial. 15 of the 17 studies reported some level of clinician, or researcher contact. This ranged from very limited initial interaction with a researcher to multiple daily support calls from a dedicated mobile interventionist. Presently, it is difficult to draw clear conclusions, as only two studies specifically reported qualitative data on the effect of the involvement of supportive online interventionists (Gleeson et al., 2014) or therapeutic alliance (Ben-Zeev et al., 2014a). However, it was clear that the interventions with limited support (e.g. ESM based studies) had lower rates of adherence by approximately 10%. In the future it would be interesting for studies to experimentally manipulate the level of support and then measure the impact on adherence, or correlate the ratings of therapeutic alliance in the intervention and the level of adherence. This will clarify the impact of social presence.

Alvarez-Jimenez et al., (2014) and Wykes and Brown (2016) recommended that service user involvement in intervention development might be an important predictor of adherence. Both groups recommend co-production as the way forward. In the current dataset only two trials included service users in the development of the intervention so it is difficult to draw conclusions about the impact on adherence. However, adherence and service user feedback from both of these interventions was very high (adherence at 86.5% and 95%). This is an important area that requires future study and analysis.

Finally, it appears that the effect of study design (observational, feasibility or RCT intervention) may slightly impact levels of adherence. Rates for RCTs (N=5, adherence to trial approximately 86%) and feasibility or observational studies (N=11, adherence to study approximately 78%) were similar although higher for the RCT designs. This indicates that participants may adhere when involved in a supported, structured controlled trial as opposed to when asked to engage with a programme or technology without the specific aim of psychosocial improvement. The five RCT's in this review varied in terms of the amount of social presence but every study had at least one contact per week with a

dedicated researcher. It is important to consider that participants recruited to RCT studies may be different from participants recruited to observational studies. Those who are willing to participate in an intensive, structured RCT may be at different stages of recovery or have different motivation (i.e. payment or extra support) than those who consent to an observational study and this could impact on adherence. For example, another area of future investigation would be to look at the impact of participant payment on adherence. Some trials may try to increase motivation to adhere to the trial through payment for participation. It would be interesting to compare rates of adherence with paid and unpaid trials.

4.4 Strengths and limitations of the review and recommendations

One of the main limitations of this study is the difficulty of comparing rates of adherence across studies with different interventions and different outcomes. Although most studies provided data either as percent of individuals completing an intervention or the mean percentage of an intervention completed, these two measures cannot be directly combined. It is therefore difficult to compare adherence levels across different types of interventions or trials. It is also difficult to compare measures of adherence because different studies may have excluded participants from the calculation of adherence if they did not met a specific threshold e.g. at least ½ or 33% of entries completed. A universal measure of adherence as proposed in previous reviews should be adopted. Christensen et al., (2009) proposed that the 'percent of adherence' may be a good universal indicator. Along with a universal measure of adherence it may also be interesting for studies to provide more detailed information on the quantity or quality of adherence. For example, Simco et al., (2014) recommended including not just the percentage of an intervention completed but the number of exercises per week, plans to continue use, or log-ins per week to get a more qualitative perspective on use. One interesting area of future research would be to examine the duration, frequency and intensity of the intervention and the affect that this may have on adherence. Trials that last for several months may have more variable adherence than those that last of only one week.

Several studies used participant feedback questionnaires, however, they were all different; some previously published but most were idiosyncratic and this variability also hinders comparison. Many questionnaires did include similar questions on satisfaction, ease of use and helpfulness of the intervention, or continued use of intervention, however, not all. A standard questionnaire specifically for web-based and mobile interventions would provide detailed and comparable information on the service user perspective and experience.

This review included different study designs and different types of interventions. It is also important to note that the narrow search terms used in this review may have limited the number of included studies, particularly ESM studies, therefore these results should be considered exploratory. In the future increases in efficacy RCTs would allow an examination of the impact of adherence on the outcome of interventions. RCTs comparing different types of mobile or internet interventions (e.g. self-monitoring, mood management, psychoeducation) will also be important to establish efficacy and suitability. Some service users may have preferences for different technologies and different intervention targets. This review was time limited. We only included studies that have been published since the previous systematic review in the field in 2013 in order to provide an overview of the most recent and relevant findings in the field and to include the next generation of mobile and web-based technologies as recommended by Alvarez-Jimenez et al., (2014) and Ben-Zeev et al., (2014). The recent boom in mobile and web-based interventions will mean that there may soon be more trials and data on adherence for mobile and web-based interventions for psychosis than the current limited dataset. It should be noted that the age of the population included in this review ranged from 18-65. Future reviews should examine separate age cohorts in order to examine the effect of chronicity of disease as well as digital literacy on adherence. First Episode Psychosis services include people aged 16 in the UK so this early age range should be included in future reviews as they are likely to be the most digitally literate group.

This review is limited in that we only examined adherence, we did not look at the effectiveness of interventions or other specific outcomes. This will be an important area to explore further as adherence may not be directly related to efficacy; some participants may stop using an intervention early because they have learned the benefit however, others may not have used it enough to receive a benefit. The relationship between adherence and efficacy may vary depending on intervention and service user. We also did not assess or compare the types of outcomes measured, for example, some studies conducted cognitive assessments and others used only measures of symptoms. In the future it will be important to compare and contrast the use of different outcome measures. Finally, this review only included English language reports.

There are some important disadvantages to consider when selecting a narrow search criteria and time frame. For example, the Cochrane Reviews Handbook (Higgins and Green, 2011) outlines how the resulting evidence for the research question may be sparse, the findings may not be generalizable to other settings, populations or interventions, and the findings may not include all of the potential relevant data. With this in mind the analysis of adherence, particularly for the ESM studies, and the preliminary analyses examining type of study i.e. comparing the ESM /Observational studies with the RCT's should be considered exploratory. Further investigation is needed to examine potential differences in adherence between these different types of studies. Here we provide an up to date review that aims to be concise and accessible. Due to the rapid growth of research in this area and the use of many new technologies this review highlighted how participants obtained high levels of adherence across many different types of studies and interventions.

In summary, this review has provided a systematic overview of the current state of adherence to mobile and internet based interventions for people with psychosis. We have assessed a range of different novel technological interventions from text message based to web based to virtual reality based programmes. Importantly, we discovered that adherence across different types of studies and a diverse range of interventions is

moderate to high. We also provide an initial exploration of theoretically proposed predictors of adherence and confirm that these would be useful and interesting areas for further exploration. The focus on service users experience is an important direction for the field.

4.5 Future directions and Implications

This review has revealed several important implications that may inform interventions and the development of a model of adherence (summarized in Table 4 below). Instead of developing new interventions, several researchers have noted that what the field of mental health desperately needs is research and strategies to support service users to engage in current evidence-based effective treatments (Christensen et al., 2009; LeClerc et al., 2015). The development of a theoretical framework that would help us to understand the barriers to accessing and maintaining treatment adherence would be extremely valuable. This theoretical model could be a multi-level framework that includes service-user-specific factors, demographic factors and the intervention factors that may best predict adherence to interventions. For example, service-user-specific predictors of adherence may indicate that older, chronic service users may more readily engage in a web-based intervention with a high level of social support whereas FEP service users may be more likely to engage with a short, independent, mobile intervention. This should be systematically investigated. It may be that older service users have developed better coping strategies but may want to work alongside clinicians and researchers whereas young service users may benefit from an initial introductory trial and then prefer an intervention they can access independently.

Along with a model of service-user or intervention predictors of adherence, the experience of the service-user may be a key factor in improving adherence. Adherence appears to be higher in studies with higher levels of social presence and in the few studies that included service user involvement in the development of the intervention. A model that combines service-user or intervention predictors with service user experience may be the best way forward. For example, Drake et al., (2015) used structural equation modeling

to examine the relationship between important predictors of adherence to medication in FEP. These included medication attitudes, self-esteem and insight. They found that low insight at first presentation predicted readmission whereas good insight at six-week follow-up also predicted remission. They recommend that a multilevel intervention that includes different psychological interventions including motivational interviewing and psychoeducation along with text message reminders for medication use would perhaps be the most effective in promoting medication adherence without risking damage to the individuals' self- concept. This is in line with recent recommendations from Mohr et al., (2011) who suggested a model of adherence to technological interventions that includes 'supportive accountability', whereby the service user is involved in a reciprocal, respectful relationship. They conclude that if this model is used the intervention is more likely to appeal and be maintained by the service use as this approach may tap into the services users' intrinsic motivation (personal objectives and self-reflection) and promote increased independence and self-determination instead of questioning the service users' competence. We propose that the service user experience may play a vital role in establishing and maintaining adherence.

Current Findings and Implications for a Model of Adherence
Specific Predictors • **Adherence to mobile and web-based interventions is not necessarily predicted by service-user specific factors such as age, symptoms, or gender; however, FEP may prefer an intervention that they can independently access** • **Adherence is moderate to high across different intervention specific factors such as amount of time to complete an entry and across different study designs however service users may prefer the smartphone interface and may adhere more in the first week of an intervention** **New Predictors** • **Adherence was higher in the interventions that provided more frequent social support** • **Service user involvement in the development of an intervention may promote adherence and satisfaction with intervention**

TABLE 4 CURRENT FINDINGS AND THE POTENTIAL IMPLICATIONS FOR A FUTURE MODEL OF COMPLEX FACTORS THAT AFFECT ADHERENCE

In conclusion, this systematic review provides an overview of how adherence is measured and rates of adherence to mobile and web-based interventions or trials for psychosis. It has been well established that these types of interventions are feasible and acceptable for this service-user group; what currently needs exploration is how to best support service users to maintain adherence with these innovative interventions. Future areas to explore include the role of service-user specific and intervention specific predictors of adherence, the role of social support and the importance of the involvement of service users in the development and assessment of mobile and web-based interventions. These will be important factors to consider as this field continues to boom and thrive using these new innovative technologies.

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APPENDIX 1

Form A: Inclusion criteria

Article ID number: Data extractor:

Title of article:

First author:

	Unclear	Yes	No
Does the study meet the inclusion criteria?	☐	☐	☐

If not, reasons:

_____

Published After August 2013	Yes	No
Study design Include primary studies only		
Systematic Review		
Primary Study		
Participants Include studies that include a participant group with at least 75% of participants with diagnosis of psychosis spectrum disorders		
Clinical group: psychosis / psychosis spectrum disorders		
Clinical group: bipolar		
Clinical group: other		
General population		

Aim of study Include studies that are web-based or mobile interventions		
<u>Intervention: web-based</u> Defined as web-based interventions enabling psychoeducation peer-to-peer contact, patient-to-expert communication or interactive psycho education/therapy; flexible, accessible monitoring, self-help, symptom management		
<u>Intervention: mobile based</u> interventions delivered via mobile phones using SMS, MSS, mobile or web-application enabling psychoeducation peer-to-peer contact, patient-to-expert communication or interactive psycho education/therapy; flexible, accessible monitoring, self-help, symptom management,		
Feasibility or acceptability study		
Other: eg traditional face to face therapy via teleconference		
Outcome measures reported Study should include at least one measure of the below		
Symptoms		
Functioning		
Cognition or metacognition		
Other outcome measures		

APPENDIX 2

Tables of Characteristics of studies and interventions

TABLE 2: Study Characteristics

a) Randomised Controlled trials with pre and post outcomes, control group

First author and year	Study Source (country)	N (%male)	Age	Specific Diagnosis (eg FEP, chronic)	Study Design	Aim of study	Control group	Outcome measures
Palmier-Claus et al., 2013b(also reported in Ainsworth et al., 2013	UK	24 (19 male)	33.04 (sd=9.5)	Non affective psychosis	Random repeated measure cross-over design	Use of smart phone or text messaging for real time assessment of symptoms	Cross over control group	Qualitative interviews to assess perceptions and experiences of devices, PANSS, Quantitative Feedback questionnaire
Van der Krieke et al., 2013	Netherlands	Intervention N=40 (13 female) TAU N= 33 (21 female)	Intervention 37 (12.35) control 40 (13.47)	Non affective psychosis, DSM Criteria	Randomized control trial	Web-based information and decision tool to help patients identify needs and treatment options	TAU	Patient-rated Combined Outcome measure for risk Communication and Treatment decision making effectiveness (COMRADE) Client Satisfaction Questionnaire (CSQ)
Kurtz et al., 2015	USA	64 Cog rem group= 26, 73% male,	Cog rem group= 36.1 (12.8), control=	Schizophrenia or schizoaffective disorder	Randomized treatment trial, quasi experimental	Social skills training combined with web-based cognitive training (COG REM)would improve memory and	TAU and social skills training combined	Neurocognitive assessment, WAIS, and others, Social skills performance

		control 73% male	37.1 (12.1)		design, blind	attention	with computer skills training instead of cog rem training	assessment, Quality of Life Scale,
Smith et al., 2015	USA	Intervention: 21 52.4% male Control: 11 54.5% male	Intervention: 40.8 (sd= 12.2) Control: 39.1 (sd= 10.6)	Schizophrenia and schizoaffective disorder	Small randomized control study, blinded raters	Efficacy of virtual reality job interview training on job outcomes and confidence	Waitlist controls	Post-test video role plays of interviews scored by blinded raters, self-report interviewing confidence, 6 month follow up data on employment outcome
Beebe et al., 2014	USA	30 (11 males) randomized into 3 groups (weekly phone calls, daily text messages or both)	48.7 (sd=11.6)	Schizophrenia spectrum disorders	Small randomized control study,	Comparing the effect of telephone calls only, text message only and telephone calls and text messages on symptoms and medication adherence	Cross over groups	Symptoms: BPRS, medication adherence scores

b) Feasibility Studies

First author and year	Study Source (country)	N (%male)	Age	Specific Diagnosis (eg FEP, chronic)	Study Design	Aim of Study	Control group	Outcome measures
Nahum et al., 2014	USA	17 with schizophrenia (76.4% male) and matched health controls	Schizophrenia (23.8, sd=3.2) control (23.6, sd=3.6)	Schizophrenia spectrum disorder	Case-control study	Feasibility of use and efficacy of a novel neuroplasticity based online training program (SocialVille)	Yes, matched healthy controls	Measures of attrition, compliance, social cognition; facial memory, emotional prosody identification, emotion and social perception, Functioning, QoL, Social and Role scales
Gleeson et al., 2014 (update of Alvarez-Jimenez, 2013)	Australia	20 (50%m)	Average 20.3	FEP	single group design	Safety of HORYZONS online psychosocial internet based intervention, including peer to peer networking, psychoeducation, online psychosocial intervention modules	no	SCID, BPRS, CDSS, BAI, Feasibility; usage of online system, User experience questionnaire, safety
Ben-Zeev et al., 2014 a	USA	17(59% male)	Average 40.47,	Dual diagnosis schizophrenia and schizoaffective disorder and substance misuse	single group design	Feasibility study, Clinical social worker sent daily text messages to assess medication and clinical status	no	usability and satisfaction questionnaire, working alliance inventory
Ben-Zeev et al., 2014 b	USA	33 (61% male)	45.9 (SD=8.78)	Schizophrenia or	single group design	Feasibility of mobile app resources to facilitate real time	no	PANSS, BDI, BMQ, acceptability/

				schizoaffecti ve disorder		illness self-management; mood regulation, medication management, social functioning, sleep, participants asked to complete assessment then intervention if required 3x daily		usability measure, correlation between symptoms and use of phone
Palmier-Claus et al., 2013a (see Palmier-Claus et al., 2012 for main study, also reported in Palmier-Claus et al., 2014)	UK	44 in total with DSM diagnosis of schizophre nia (18 male), 12 of which with ultra high risk of psychosis (10 male)	Acute: 36.8 (sd= 10), remitted 35.5 (sd 8.) UHR 22 (sd=4.4)	Acute schizophren ia and remitted, UHR	3 groups of patients with different levels of psychosis	Feasibility of a mobile phone based momentary assessment in individuals with psychosis for clinical management and research purposes	none	Calgary Depression Scale, Momentary assessment scales, PANSS
Ventura et al., 2013	USA	9	NA	Schizophren ia, clinically stable	Pilot single group design	Acceptability of PositScience's internet based Brain Fitness program using auditory discrimination tasks	None	MATRICS neuro-cognition, Clinical Global Impression of Cognition in Schizophrenia, Brief Questionnaire on Knowledge of Cognition, Outcome rating scale

c) Observational/Experience Sampling Method Studies

First author and year	Study Source (country)	N (%male)	Age	Specific Diagnosis (eg FEP, chronic)	Study Design	Aim of Study	Control group	Outcome measures
Brenner and Ben-Zeev 2014	USA	24 (71% male)	44.88 years (sd=9.27)	Schizophrenia or schizoaffective disorder	single group design	Hand-held device to prompt in the moment ratings of positive and negative affect	no	Comparison of baseline scores and momentary affective forecasting throughout the week
Kimhy et al., 2014a	USA	77 individuals with schizophrenia, 27 healthy controls	Schizophrenia 32.15 years (sd=9.19) Control 23.95 (sd= 5.01)	Schizophrenia spectrum disorder	Case-control study	Rating of momentary emotions (sadness, anxiety, anger, happiness) using mobile electronic devices	Yes, healthy controls	Measures of emotional granularity from ESM responses and social functioning: PSRS, interview, ability task MSCEIT) Toronto Alexithymia scale, Difficulty identifying feelings, Test of reading ability; WTAR, BAI, BDI, Symptoms; SAPS, Neurcog; MATRICS
Hartley et al., 2014	UK	32 (male 22)	33 years (sd=10.7)	Schizophrenia spectrum disorders, 3+ on the PANSS for hallucinations	single group design	Using ESM using a palm computer to capture whether worry and rumination are associated with persecutory delusions and hallucinations	none	Metacognitions around worry; Negative beliefs about ruminations scale, Meta-worry questionnaire,
Kimhy et al., 2014b	USA	33 inpatients (15 female)	27.8 years (sd= 6.3)	Schizophrenia spectrum disorders, in patient	single group design	The use of mobile devices to monitor symptoms in inpatient environments	none	Self-report rating of mood and symptoms

				setting				
So et al., 2013	China and UK	26 inpatients (50% male)	36.12 years	In-patients with acute delusions scoring 4+ on the PANSS, schizophrenia spectrum disorder	single group design	The use of mobile devices (PDA) to monitor symptoms in inpatient environments after the introduction or reintroduction of anti-psychotic medication	none	Symptoms: SAPS, PANSS, PSYRATS
Sanchez et al., 2014	USA	Schizophrenia N = 47, (35 male) healthy controls (26 male) N=41	Schizophrenia 39.55 (13.95) control: 36.83 (14.89)	Schizophrenia and Schizoaffective disorder	Case-control study	Ecological momentary sampling to examine the relationship between emotion experience and environment	Healthy control group	PANSS, MATRICS neurocognitive battery

TABLE 3: Characteristics of Interventions and rates of adherence

a) Randomised Controlled trials with pre and post outcomes, control group

First author and year	Length of study	Adherence Measure and rate	Dropout rate	Type of social presence	Frequency of social presence	Service user involvement in development	Measure of participant feedback and rating of acceptability
Palmier-Claus et al., 2013b (also reported in Ainsworth et al., 2013)	4 x a day for 6 days	% of participants completing the intervention: 88, (across all participants)	1 asked to have SMS stopped 2 days early due to ruminati on	Once or twice per week based on participants preference	Once or twice per week based on participants preference	Participants were interviewed about their experience	Qualitative interviews with range of perspectives on usability, all participants completed the feedback assessments
Van der Krieke et al., 2013	6 weeks, self-directed use of website	% of participants completing the intervention: 71% used full functionality of the website	10 dropped out	Assist was available to answer questions over the phone anytime	3 days a week	Open interviews with 15 patients to evaluate the intervention	30 used the web program
Kurtz et al., 2015	Cog Rem treatment: 50 min/day 3 days/week for 23 weeks SST: 50min/day, two days/week,	% of participants completing the intervention: 100%, (min criteria for inclusion; all individuals	All participa nts complete d at least one session	Interaction with clinician for both Cog Rem and Computer Skills training groups SST group: 2x	NA	NA	SST Mean number of sessions= 32.3 COG REM Mean number of sessions= 31.9

	for 23 weeks Computer skills: Target 50 hours over 23 weeks	received at least one session)		per week for 50 min, led by researchers			Computer skills=Mean number of sessions= 32.2
Smith et al., 2015	Up to 10 hours of virtual interviews over the course of 5 visits	Average % of entries completed: 90% of sessions attended and completed	2	Basic contact during computer intervention	During intervention only briefly	None reported	90% attendance rates of sessions
Beebe et al., 2014	3 months	Average % of entries completed: 81.60 (across all participants)	2	Various: weekly telephone calls, daily text messages, both	various	None reported	Phone calls plus text message group higher adherence by an average of 5.3%

b) Feasibility Studies

First author and year	Length of Intervention	Adherence Measure and rate	Dropout rate	Type of social presence	Frequency of social presence	Service user involvement in development	Measure of participant feedback and rating of acceptability
Nahum et al., 2014	Total of 24 hours of online	% of participants completing the	7 dropped out	None reported	None reported	Subjects rated their satisfaction in	On average subjects took 8.1 weeks to

	training, 1-2 hours per day for 6-12 weeks	intervention: 78 (completed 24 hours of the intervention across all participants)				the training program	completed the 24 hours of training,
Gleeson et al., 2014 (update of Alvarez-Jimenez, 2013)	1 month	% of participants completing the intervention: 60 (completed at least 3 modules eg 33%)	None: All accessed modules	Peer to peer online social networking Coaches (expert moderator)	Coaches moderated online activity 2 hours/day weekdays, 1h/day weekend	Developed with service user focus group	70% completed 30weeks, 60% completed > 3 online therapy modules 75% reported a positive experience
Ben-Zeev et al., 2014a	12 weeks	Average % of entries completed: 87.00 (average response rate to text messages for all participants)	2 drop outs	Mobile interventionist: clinical social worker	Daily, up to 3 text messages a day	None described	On average participants responded to 87% of messages, 90% rated the intervention easy to use, useful and fun
Ben-Zeev et al., 2014 b	1 month	Average % of entries completed:86.5 (rate of access to the system for all participants)	1 dropout,	Researcher called participant to check in and assist with technical difficulties	1x/week	Developed through service user feedback	90% rated the intervention as highly acceptable, 12% reported it was a complicated intervention, reductions in symptoms

							PANSS and BDI
Palmier-Claus et al., 2013a (see Palmier-Claus et al., 2012 for main study, also reported in Palmier-Claus et al., 2014)	6x a day for 7 days	Average % of entries completed:72 for those who were compliant with the intervention (eg completed 33% of data)	8	Researcher telephoned participant at least once per week to offer advice and encouragement	Once or twice per week based on participants preference	None described	82% of participants met compliance criteria of completing at least 33% of the entries
Ventura et al., 2013	6 weeks, 2 hours/week	Average % of entries completed: 75(response rate across all participants)	1	Regular phone contact with the study team	NA	None reported	5 participants completed 12 or more sessions (75% of patients reached adherence criteria)

c) Observational/Experience Sampling Method Studies

First author and year	Length of Intervention	Adherence Measure and rate	Dropout rate	Type of social presence	Frequency of social presence	Service user involvement in development	Measure of participant feedback and rating of acceptability
Brenner and Ben-Zeev 2014	6x a day for 7 days	Average % of entries completed:98.10 (response rate across all participants)	none	Researcher called participant to check in and assist with technical difficulties	2x/week	None described	Response rate 98.1%
Kimhy et al., 2014a	10x a day for 2 days	Average % of entries completed:79.15 (response rate across all participants)	29 patients	None reported	none	None described	Not reported
Hartley et al., 2014	10x a day for 6 days	Average % of entries completed: 59 (response rate for completers; completion of the schedule defined as completing at least half of the entries (n=27))	5 dropped out	During the 1st day patients contacted to ensure functional equipment	Once in a week, but if needed additional phone contacts were arranged	Feedback questionnaire about involvement	
Kimhy et al.,	10x a day for 1 days	Average % of entries	1	Introduction session for 20	None reported	None reported	81% response rate

2014b		completed: 81 (response rate for all participants)		min on first day			
So et al., 2013	14 days 7x a day, randomly	Average % of entries completed:70.7 (response rate in participants who completed at least 1/3 of entries)	5	Contacted by researcher at least 2x during 1st week, to offer support and remind to change battery	Participants were encouraged to contact researcher by phone if problems	None reported	16 participants met criteria for minimum compliance, completing 30 or more diary entries
Sanchez et al., 2014	Phone call 4x a day for 7 days	Average % of entries completed: 80.16 (response rate for all participants with schizophrenia)	None reported	Participants were called 4x a day	4x a day, each call patient was interviewed about their environment, goals, activities	None reported	Response rate to calls was 80.6% in patients and 81.3% in controls

APPENDIX 3

Trial Quality Characteristics

Table 1 CTAM (2004) Assessment for RCT and Feasibility studies

First author and year	**Total CTAM (max 100)**	**Sample (Q1, Q2) (max 10)**	**Allocation (Q3,Q4,Q5) (max 16)**	**Assessment (Q6,Q7,Q8,Q9,Q10) (max 32)**	**Control (Q11) (max 16)**	**Analysis * (Q12,Q13) (max 15)**	**Treatment description (Q14,Q15) (max 11)**
***Gleeson et al., 2014**	44	2,0= 2	0	10,6,0,0,0= 16	0	5,6,4= 15	3,3,5= 11
***Ben-Zeev et al., 2014 a**	36	2,0=2	0	10,6,0,0,0= 16	0	5,6,4= 15	3,0,0,= 3
***Ben-Zeev et al., 2014 b**	44	2,5=7	0	10,6,0,0,0= 16	0	5,6,4= 15	3,3,0= 6
***Nahum et al., 2014**	44	2,0= 2	0	10,6,0,0,0=16	0	5,6,4=15	3,3,5=11
***Palmier-Claus et al., 2013a (see Palmier-Claus et al., 2012 for main study, also reported in**	39	2,0=2	0	10,6,0,0,0,=16	0	5,6,4=15	3,3,0=6

Palmier-Claus et al., 2014)							
Palmier-Claus et al., 2013b (also reported in Ainsworth et al., 2013	62	2,0=2	10,3,0=13	10,6,0,0,0=16	10	5,6,4=15	3,0,3=6
Van der Krieke et al., 2013	78	2,5=7	10,3,0=13	10,6,10,0,0=26	6	5,6,4=15	3,3,5=11
***Ventura et al., 2013**	44	2,0=2	0	10,6,0,0,0=16	0	5,6,4=15	3,3,5=11
Kurtz et al., 2015	88	2,5=7	10,0,3=13	10,6,10,3,3=32	10	5,6,4=15	3,3,5=11
Smith et al., 2015	79	2,0=2	10,3,0=13	10,6,10,3,3=32	6	5,6,4=15	3,3,5=11
Beebe et al., 2014	75	2,0=2	10,3,0=13	10,6,10,3,0=29	10	5,6,4=15	3,3,0=6

*Indicates the study is designed as a Feasibility or Acceptability trial. For Ratings of treatment description: Q14 score 3 if website or mobile interface adequately described; for ratings of handling of dropouts, if dropouts described and reasonably analysed score of 4 given

Table 2 Trial Quality Characteristics for non-randomized controlled trials: Downs and Black (1998) Ratings

Checklist Question	Brenner and Ben-Zeev 2014	Kimhy 2014a	Kimhy 2014b	Hartely 2014	So 2013	Sanchez 2014
Question 1	1	1	1	1	1	1
Question 2	1	1	1	1	1	1
Question 3	1	1	1	1	1	1
Question 4	1	1	1	1	1	1
Question 5	2	2	2	2	2	1
Question 6	1	1	1	1	1	1
Question 7	1	1	1	1	1	1
Question 8	1	1	1	1	1	0
Question 9	1	0	1	0	1	0
Question 10	0	1	1	1	1	1
Question 11	0	UTD[4]	UTD	0	1	1
Question 12	0	UTD	1	1	1	0
Question 13	1	1	1	1	1	1
Question 14	0	0	0	0	0	0
Question 15	0	UTD	UTD	UTD	0	UTD
Question 16	1	1	1	1	1	1
Question 17	1	1	1	1	1	1
Question 18	1	1	1	1	1	1
Question 19	1	1	1	1	1	1
Question 20	1	1	1	1	1	1
Question 21	1	1	1	1	1	1

[4] Unable to determine

Question 22	1	1	1	1	1	UTD
Question 23	0	0	0	0	0	0
Question 24	0	0	0	0	0	0
Question 25	0	1	1	1	1	1
Question 26	1	UTD	UTD	1	1	0
Question 27	0	0	UTD	1	1	0
TOTAL	**19**	**19**	**21**	**22**	**24**	**17**

APPENDIX 4

PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	19
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	14
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	17
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	47-56
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	19
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	19-27

Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	na
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	19
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	20-27
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	28-32
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	32
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	34
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	na

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

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Chapter 2: Main Research Project

The effect of self-monitoring using a novel mobile technology and intervention on metacognition in people with schizophrenia

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Dr Clare Reeder
Dr Jo Neale

Abstract

Background: Metacognition, or the ability to reflect on one's thoughts and knowledge, is found to be impaired in people with schizophrenia, and may underlie deficits in clinical and cognitive insight into mental disorder. Researchers have proposed the 'digital placebo effect' (Torous and Frith, 2016): the use of a digital device indirectly improves symptoms of mental disorder. We examined if an intensive, real-time self-monitoring intervention indirectly improves insight, i.e. understanding of mental disorder, in people with schizophrenia.

Methods: A mixed methods feasibility design was adopted. Participants were allocated to one of two conditions (i) recording their symptoms four times a day for a 12 week period using the 'ClinTouch' mobile phone application (app) in addition to treatment-as-usual (Experimental group) or (ii) Treatment-as-usual (TAU) alone. Participants were asked to complete baseline and week 12 measures including the Beck Cognitive Insight Scale (BCIS), CHOICE cognitive behavioural therapy scale and the Scale of Unawareness of a Mental Disorder (SUMD-A). 15 participants from the experimental group consented to a brief qualitative interview about their experience of self-monitoring. We examined descriptive statistics and trends in the data for improved insight for the experimental group. This was expanded on by insight related themes from the qualitative interviews.

Results: 44 participants with a diagnosis of a psychotic disorder were recruited from outpatient services to two groups (Experimental group N=22, TAU N=22). There were no statistically significant differences between the groups on insight variables at week 12, however, the experimental group showed trends for improved insight on variables of the SUMD-A and BCIS and significantly improved positive symptoms compared to the control group. The qualitative analysis highlighted that all participants reported either they 'developed a new understanding' or 'emerging self–reflection'. Participants varied in terms of their adherence to the self-monitoring protocol. Trends in the data suggest that greater use of the app led to decreased insight and higher symptoms.

Conclusions: This research project provides limited statistical evidence supporting the hypothesis that self-monitoring indirectly improves metacognition. Metacognition may be better measured using a questionnaire that takes into account themes such as 'emerging insight' or 'noticing of patterns'. The adherence data suggests that participants who stopped using the app may have begun to develop insight, notice their symptoms increase and found this unhelpful. In contrast participants who continued to use the app may have needed more time and support to develop an understanding of their experiences. This is the opposite of the predicted 'digital placebo effect' as people may indirectly experience worsening of symptoms and less insight the longer they use the app. Future research should unpick both the positive and negative effects of mobile self-monitoring and for whom the intervention is best suited.

Chapter 2 Table of Contents

List of Tables for Chapter 2

List of Figures for Chapter 2

1. Introduction

Schizophrenia is one of the most debilitating neuropsychiatric disorders as symptoms typically emerge in young adulthood and relapse is common throughout the lifetime. Symptoms include disturbance in thinking, disorganized speech, flat affect, lack of volition along with symptoms of psychosis; hearing voices and/or delusions (World Health Organization, 2016). 80% of people who develop a first episode of schizophrenia will relapse within 5 years (Robinson et al., 1999). Each episode of relapse significantly increases the risk for additional episodes (Wiersma, Nienhuis, Slooff, & Giel, 1998) and increases impairment in functioning and quality of life (Penn, Waldheter, Perkins, Mueser, & Lieberman, 2005). Research is needed that targets effective relapse prevention in order to promote recovery.

1.1 Relapse Prevention: the importance of 'insight'

There are several risk factors that predict relapse including non-adherence to medication, persistent substance abuse, carers' criticisms, and poor premorbid adjustment (Álvarez-Jiménez et al., 2012). In a systematic review Lacro et al. (2002) found a non-adherence rate to psychological and pharmacological treatment of 47% and concluded that one of the most highly reported, yet potentially amendable predictors of non-adherence was poor insight into having a mental illness (Drake et al., 2007).

1.1.1 Clinical and Cognitive Insight

A pivotal study by Amador and Gorman (1998) found that 50-80% of people with schizophrenia did not believe that they had a mental illness. Insight is a term that may refer to different dimensions such as; awareness of having a mental disorder, awareness of the effects of medication, and understanding the consequences of disorder (Amador Strauss & Yale, 1993; David, 1990). Impaired insight has been found to lead to poorer psychosocial functioning, poor adherence to psychiatric treatment and increased severity of positive and negative symptoms in people with schizophrenia (Amador et al., 1994; Pini, Cassano, & Dell'Osso, 2001). It is thought to be one of the

main factors contributing to treatment non-adherence and relapse in schizophrenia (Henriksen & Parnas, 2014).

Beck et al., (2004) make the important distinction between *clinical insight* and *cognitive insight*. *Clinical insight* is described above; awareness of having a mental disorder, the effects of medication and psychosocial consequences and is measured by scales such as the Scale for the Unawareness of Mental Disorder (SUMD) (Amador et al., 1993). Beck et al., (2004) argued that these scales miss out on the cognitive processes that may contribute to impaired insight, such *cognitive insight* or the ability to evaluate, detect and correct misinterpretations about their experience. The higher order evaluative process of cognitive insight may be an important mediator of improved clinical insight and therefore functional outcomes and relapse prevention.

Donohoe et al., (2009) investigated whether illness awareness (clinical insight) was related to other aspects of self-awareness such as cognitive self-monitoring or awareness of errors. They found that those with better clinical insight, as measured by the Schedule for Assessment of Insight (SAI) (David, 1990), also had more cognitive insight into their performance on neuropsychological tasks. Support for a distinction between clinical and cognitive insight comes from a study which found that each affected different symptoms (Greenberger & Serper, 2010). Those with higher cognitive insight were found to have less severe preoccupation with symptoms and whereas those with higher clinical insight had increased depression symptoms. Underpinning the development of cognitive and clinical insight is thought to be a core cognitive skill; metacognition (David, Bedford, Wiffen, & Gilleen, 2012; Lysaker et al., 2005)

1.1.2 Underlying deficit in Metacognitive Regulation and Knowledge

Lysaker et al., (2005) found that poor insight into mental illness was related to deficits in the core cognitive skill 'metacognition'. This is the ability to reflect on one's thoughts and knowledge and has also been found to be impaired in people with schizophrenia (Bentall, 1990; Vohs & Lysaker, 2014). Metacognition involves two important components including *regulation* and *knowledge* (Schraw & Dennison, 1994)

(see Table 1 for summary of definitions). Metacognitive regulation is the process of monitoring and regulating your own cognition. Frith (1992) suggested that those with schizophrenia have lost some of the ability to think about thoughts and feelings in a reflective and meaningful way; for example, hearing voices may result from impairment in the ability to represent your own or others mental states and may lead to the misattribution of internal events as external. Metacognitive knowledge is knowledge or understanding about how the mind functions and beliefs about your own mind or cognition (e.g. I have a good memory). Morrison, Haddock, & Tarrier (1995) suggested that people with schizophrenia have incorrect knowledge or beliefs about the controllability of thinking that may lead to hallucinations such as thought insertion. Clinical and cognitive insight relates to beliefs and knowledge that is specific to a mental health disorder (such as knowledge of the consequences of disorder i.e. social isolation and knowledge of errors in thinking i.e. I cannot trust people). Therefore deficits in both areas of metacognition (regulation and knowledge) may underlie both types of insight and may be a significant barrier to acquiring new knowledge that may be important for recovery and relapse prevention.

1.1.3 The putative key to improved insight: self-monitoring

There may be several different pathways to improved awareness of symptoms and behaviour. Previous research has suggested that better self-esteem (Cella, Swan, & Medin, 2014; Paul H Lysaker et al., 2011), improved mood, lower positive and negative symptoms (Palmier-Claus, Taylor, & Gooding, 2012) and metacognitive training (Moritz et al., 2014) are associated with higher clinical and cognitive insight. Reeder, Rexhepi-Johansson, & Wykes (2010) suggested that what is important for an individual's functional outcome is not necessarily the metacognitive belief that an individual holds (i.e. I have a poor memory) but how this affects real life functioning (i.e. I should rehearse and monitor my memory). Metacognitive regulation and the process of actively monitoring your own cognition, may guide behavior and cognitive resources more efficiently (Cella et al., 2014; David et al., 2012; Flavell, 1979). David et al., (2012) suggests that the act of monitoring may reveal abilities or impairments that lead to an adjustment of self-knowledge.

Increasingly there is support for the role of self-reflection in relapse prevention and recovery (Henriksen & Parnas, 2014; Lysaker, McCormick, & Snethen, 2011). Lysaker has criticized the traditional approach to recovery and relapse prevention as focusing mainly on the reduction of observable symptoms whereas equally important is the capacity to understand the self and others (Lysaker & Dimaggio, 2014). Pitt et al., (2007) found, from a service user perspective, recovery meant a better understanding of oneself and feelings of empowerment. Meaningful recovery goes beyond a decrease in measureable symptoms and entails the ability to recapture a coherent understanding of oneself (Connell et al., 2015). It is important to consider that recovery may have different meanings for different individuals; it could mean a decrease in symptoms for some or the ability to understand and live with symptoms for others. The key mechanism may be self-reflection and the development of an integrated understanding of experiences (Lysaker et al., 2015).

TABLE 1 DEFINITIONS OF KEY TERMS AND MEASURES

Term	Definition	Measure
Metacognitive Regulation	The process of self-monitoring and reflection on one's own thinking	-Adherence to the self-monitoring protocol -Qualitative Interview
Metacognitive Knowledge[5]	Understanding and beliefs about one's own thinking, experiences, and how the mind works	-Knowledge and beliefs assessed through SUMD-A and BCIS -Qualitative Interview
Specific metacognitive knowledge a) Clinical Insight	Awareness of having a mental disorder, reasons for use of medication and psychosocial consequences	-Scale to Assess Unawareness of Mental Disorders - Abbreviated (SUMD-A)
Specific metacognitive knowledge b) Cognitive insight	Ability to evaluate, detect and correct misinterpretations about ones thinking and experiences	-Beck Cognitive Insight Scale (BCIS)

[5] For simplicity the general term 'insight' will be used to refer to both (clinical and cognitive) types of metacognitive knowledge throughout the methods and results sections

1.1.4 'The Digital Placebo Effect'

Recently, investigators have noted a phenomenon whereby participants report improved symptoms and functioning after using a mobile application that had no explicit or direct therapeutic intervention. For example, Kauer et al., (2012) found that after monitoring mood and recording symptoms using a smartphone app, adolescents with depression experienced a significant improvement in symptoms. Torous and Frith (2016) coined the term 'digital placebo effect', whereby the individual experiences positive effects as a by-product of using mobile mental health applications. They suggest that this placebo effect is a combination of various processes that we have yet to fully understand. However, psychological theory would suggest that the act of monitoring leads to increased understanding of external and internal states (Burnette, O'Boyle, VanEpps, Pollack, & Finkel, 2013). This can result in improved health management for example, diabetes control (van Vugt, de Wit, Cleijne, & Snoek, 2013), HIV medication adherence (Smith, Hull, Israel, & Willson, 2003) and weight loss (Hutchesson, Tan, Morgan, Callister, & Collins, 2016).

Instead of an unknown 'placebo effect', one of the key processes may be the modification of peoples' beliefs and expectations. A daily medication tracker could lead to better understanding of the effects of medication, or a longitudinal mood-monitoring app may yield an improvement in reported mood states due to awareness of different triggers and daily fluctuations. The potential for mental health apps to indirectly improve the symptoms and functioning of individuals with schizophrenia is a promising area of research.

The current study explored the notion that the 'digital placebo effect' may result from changes to peoples' beliefs and understanding about their illness. This current work suggests that intensive self-monitoring with a mobile app may indirectly lead to improved insight into mental health disorder.

1.2 Mobile Technology interventions and Metacognitive Measures

1.2.1 Novel Mobile phone app: Clintouch

A multi-centre research study undertook a proof of concept feasibility trial[6] to examine the use of a new mobile technology called ClinTouch. ClinTouch is a mobile phone application that supports self-monitoring of symptoms and mood by alerting, collecting, recording and uploading self-report patient information on symptoms and mood. Four times a day, service users responded to mobile phone prompts and were asked fill out a series of 18 questions about their current symptoms and mood. The feasibility, safety and validity of using similar new mobile technology has been previously tested (Ainsworth, Palmier-Claus, & Machin, 2013; Palmier-Claus et al., 2012). The ClinTouch technology was designed to create real time alerts for health care workers as it can actively track early warning signs and prompt early intervention when there is increased risk of suicide or deliberate self-harm. Along with facilitating crisis intervention from health care professionals, mobile phone based assessments require the participant to engage in increased evaluation of symptoms, mood and behaviour therefore increased self-monitoring. This current research study was an addition to the larger multisite proof of concept study and specifically explored how intensive self-monitoring using the ClinTouch app may prompt metacognitive regulation and lead to improved clinical and cognitive insight.

It is important to note that the aim of the larger multi-site project was to examine the feasibility of using the Clintouch mobile app along with a new intervention called CareLoop. CareLoop is a new website based technological interface that was developed as a staff intervention. When the service user received the ClinTouch mobile phone a new account for that service user was set up on the CareLoop website by the keyworker or care coordinator from the community mental health team. This online account received up to date symptom information from the ClinTouch mobile app, and used a formulae to detect individualised and generalised signs of relapse and Deliberate Self-Harm (DSH). If signs of relapse or DSH are detected the server

[6] http://www.hra.nhs.uk/news/research-summaries/poc-feasibility-trial-of-clintouch-careloop-enhanced-management/

generates an email alert which was sent to key worker and duty worker recommending intervention. All of the participants recruited to this current smaller exploratory study partook in both the ClinTouch and CareLoop intervention. An analysis of the CareLoop data was beyond the scope of this project however it is an important consideration when considering the analysis of adherence, as discussed in the limitations sections

1.2.2 Measuring Metacognition

Metacognition consists of two main components; 1) **regulation** or the process of monitoring and evaluating thinking (e.g. thoughts or beliefs about symptoms) as well as 2) **knowledge** or beliefs and understanding of thoughts and experiences (Quiles, Verdoux, & Prouteau, 2014).

Metacognitive regulation was measured by examining adherence to the ClinTouch mobile phone protocol as detailed in the methods section 2.4.1.These four different measures of adherence were used as it is anticipated that the level of adherence would vary i.e. different participants may use different strategies. For example, some participants would fully adhere for the first week and then decline in their entries, some would use the app regularly, but not four times a day, and others would adhere less initially and then engage fully by week 12. As this was an exploratory study, analyses of these four measures helped to profile the nature of adherence to this protocol.

Metacognitive knowledge was measured using three different scales in order to capture the complexity of knowledge and insight into mental illness. As suggested by Beck (2004), insight is not just awareness of a mental disorder, but also awareness of errors in thinking and an alternative understanding of experiences. Clinical insight was measured using the Scale of Unawareness of Mental Disorder-Abbreviated (SUMD-A) (Michel et al., 2013); cognitive insight was measured using the Beck Cognitive Insight Scale (Beck, 2004); finally, the CHOICE cognitive behavioural therapy measure was used to captures any changes in awareness or improved understanding of the connection between mood, symptoms and behavior. The CHOICE scale is found to

have specific factors relating to service users self-reported experience of coping and recovery (Greenwood et al., 2010). These three measures have high reliability and validity, have been specifically designed for use by service users with schizophrenia, are fast to administer and have been used extensively in the literature. Appendix 1 presents examples of the measures in the form of a Case Report form (CRF).

In addition to these questionnaire measures, service users were interviewed about their understanding and experience of schizophrenia, and their experience of self-monitoring using the app. Qualitative research on service users perceptions and experiences of mobile and internet based apps explored any themes or narratives of insight that were not captured by the questionnaires (Palmier-Claus et al., 2013; Drake et al., 2012).

1.3 Aim

The primary aim of this exploratory study was to assess if an intensive, real-time self-monitoring intervention could indirectly prompt metacognitive regulation and therefore improve clinical and cognitive insight in people with schizophrenia. This study used both quantitative and qualitative methods:

- Hypothesis 1) *Will self-monitoring improve insight measures at week 12*? It was hypothesized that intensive self-monitoring would result in improved insight, as measured by three different questionnaires, at week 12; the BCIS, SUMD-A and the CHOICE measures.
- Hypothesis 2) *Will adherence to the protocol lead to improvements in insight and symptoms?* It was hypothesized that high levels of self-monitoring, as measured by high levels of adherence to the ClinTouch protocol, would lead to increased insight at week 12.
- Hypothesis 3) *Will improved insight lead to change in symptoms and functioning?* It was hypothesized that improved insight would lead to improved PANSS positive symptoms, but worse depression symptoms.

To better inform the quantitative hypotheses, brief structured qualitative interviews of participants' experiences of self-monitoring were also conducted. These were used to

complement and expand on the quantitative data by exploring interview topics of clinical insight, cognitive insight, and metacognitive regulation.

2. Method

2.1 Study Design

A mixed methods design was adopted whereby quantitative data is complemented and expanded upon with qualitative data (Morgan, 1998). This was a longitudinal, exploratory study with participants drawn from two sources and comparing an experimental group (self-monitoring with ClinTouch mobile app for 12 weeks) with a treatment as usual (TAU) group. 44 participants were recruited across two sites (London and Manchester see below) and were allocated to the experimental (n=22) or TAU groups (n=22). As not all participants were randomly allocated baseline differences between the groups were examined using independent samples t-tests. Both groups were assessed at baseline and week 12 on measures of metacognitive insight, symptoms and functioning. After ethical approval had been granted for an amendment to include the brief qualitative interviews[7], 15 participants remained in the experimental group and all of these participants consented to the interview. Assessments were not blind to group allocation.

Ethical approval for this study was granted by NHS Ethics, NRES Committee West Midlands-South Birmingham by a substantial amendment to the Proof of Concept (PoC) Feasibility Trial of ClinTouch-CareLoop Enhanced Management (CEM) versus Management As Usual (MAU) in people with schizophrenia, REC reference: 14/WM/0045, dated November 21 2014 (see Appendix 9 for letters of approval and Appendix 2 for examples of consent form and participant information sheet).

[7] Ethical approval for an amendment which included the brief qualitative interviews was granted in May 2015 after recruitment had begun in January 2015, please see appendix 9

2.2 Participants

Sampling

41 Participants were recruited from the Croydon Outreach Assessment Support Team (COAST) in South London and Maudsley (SLaM) in south London. This is an early intervention community mental health team for people with psychosis. Three participants were recruited from South Mersey Community Activity Team in MMHSCT in Manchester which is a treatment and recovery community mental health team for people with psychosis.

Inclusion/Exclusion criteria

Participants were invited to participate in the study if they met the following criteria:

1. Diagnosis of schizophrenia or related psychotic disorders, meeting or having met the Diagnostic Statistical Manual-IV criteria for such a diagnosis
2. Aged between 18 and 65 years
3. Able to provide written and witnessed informed consent
4. Can read and write in English at a level sufficient to understand and complete study related procedures
5. Not acutely unwell at point of study entry

Exclusion Criteria

1. Current inpatient status
2. Unable or unwilling to give written consent

Sample size:

For an exploratory study the sample size should be adequate to estimate the critical parameters to the necessary degree of precision. Considering a drop-up rate of approximately 10%, a sample size of 22 per group will ensure 20 completers per group, as recommended by sample size for exploratory studies focusing on parameter estimates (e.g standard deviation and confidence intervals) (Hertzog, 2008).

2.3 Measures

Insight measures

Clinician/Researcher report: SUMD-A (Michel et al., 2013)

This 9-item scale has three subscales; *Mental disorder index* (MD), *Positive symptom index* (PS) and *Negative symptom index* (NS). Service users are rated by the clinician or researcher on a three point scale (1= Aware, 2=slightly unaware, 3= seriously unaware) for each of the 9 items. The key measure is the sum total of scores across all 9 items. The index scores for the three subscale measures are calculated based on the sum total of specified items. As cited in the study by Michel et al., 2013, the abbreviated measure has high item-internal consistency (Pearson's coefficients from .79 to .90) and high reliability (Cronbach's alpha coefficients from .76 to .83). Additionally, it showed medium to high external validity with the PANSS scale (r=.25 to .55). This clinician-rated scale provides an objective measure of insight that can be compared with participant self-report measures.

Participant report: The Beck Cognitive Insight scale (BCIS) (Beck et al., 2004)

This 15-item self-report scale includes subscales of self-reflectiveness and self-certainty as well as a composite scale (self-reflexivity minus self-certainty) to provide an overall insight measure. The subscales of *self-reflectiveness* and *self-certainty* are calculated by summing the specified questions. Higher scores on this composite measure indicate more insight. As discussed in the original study by Beck et al., (2004) large to moderate effect sizes were found when correlated with the SUMD-A and this is thought to show sufficient convergent validity for a research-based scale. Additionally there was good construct validity, r=.65, correlating change in symptom scores with insight scale scores.

Participant report: CHOICE (Greenwood et al., 2010)

This questionnaire contains 21 items that are rated by self-report from 0-10 on two dimensions (severity and satisfaction). This yields two subscales; the *satisfaction*

subscale and the *severity of distress subscale*. Higher values indicate better functioning on both subscales. As reported in the study by Greenwood et al., (2010) this measure has high internal consistency (e.g. Cronbach alpha =.83 for severity and .88 for satisfaction dimensions). It has high reliability (test-retest ICC = .73 95% CI = .51-.86, P< .001) for severity and (ICC = .79 95% CI = .61-.90 p<.001) for satisfaction.

Symptoms

The Structured Clinical Interview-Positive and Negative Syndrome Scale, SCI-PANSS, (KAY, FISZBEIN, & OPLER, 1987) is a 30-item rating scale rated by the clinician or researcher based on service users' responses to a series of questions pertaining to the last seven days. It is subdivided into three symptom categories: *positive symptoms* (e.g. delusions, hallucinatory behaviour), *negative symptoms* (e.g. blunted affect, emotional withdrawal), and *general symptoms* (e.g. anxiety, depression). Researcher CK completed a PANSS training course and was certified as a PANSS rater by the PANSS Institute (US) (January 2015). CK and another PANSS trained researcher (ZH) established high interrater reliability (Interclass correlation coefficients > 0.80).

Functioning

The *Global Assessment of Functioning, GAF* (American Psychiatric Association, 1994) is a standardised measure used to assess overall level of functioning on a scale from 0-100. The clinician or researcher makes an overall judgment about current and highest level of psychological, social, and occupational functioning based on level of functioning at the time of evaluation. Researcher CK consulted guidelines for the ratings using the GAF (Caldecott-Hazard & Hall, 1995).

2.4 Quantitative Analysis

Exploratory studies are used to estimate important parameters needed to design the main study. According to Lancaster, Dodd, & Williamson, (2004) the analysis of a exploratory study should be mostly descriptive with the main focus on parameter estimates such as standard deviation and confidence interval estimation. Therefore, throughout the results section the word 'trend' is used with the intent to draw the

readers' attention to potentially notable, but not statistically significant effects (i.e. p values <.15). Statistically significant effects are noted at the traditional threshold (p values < .05). As this study is an exploratory study we have refrained from controlling for multiple testing. The traditional feasibility estimates of methodology such as parameters of recruitment, attendance and retention rates will not be covered in this report as this will be reported by the larger multisite Careloop/ClinTouch Proof of concept trial.

2.4.1 Statistical methods

Baseline Analysis:

All statistical analyses were conducted in SPSS version 22. Inspection of histograms and the Kolmogorov–Smirnov test statistic (i.e. significance indicates that the distribution of the data significantly differs from a normal distribution) was used to determine whether parametric or non-parametric testing was appropriate. As not all the sample was randomly assigned to experimental or TAU groups, baseline differences between groups were examined using independent samples t-tests. Welch's t-test for unequal sample size was used to examine baseline differences between drop out and adherent participants.

Exploratory Analysis:

Hypothesis 1: Will self-monitoring improve insight measures at week 12?

The first aim was to determine if intensive self-monitoring resulted in improved insight, as measured by three different insight questionnaires at week 12. Three separate ANCOVAs comparing groups (experimental vs. control) at week 12 on outcome measures (SUMD-A, BCIS and CHOICE questionnaires) while controlling for baseline questionnaire scores were used to detect changes in insight. However, these results will be reported and interpreted with caution as hypothesis testing is not generally recommended for exploratory studies due to the small sample size (Arain, Campbell, Cooper, & Lancaster, 2010).

The means and confidence intervals (CI) are presented to examine if there are any trends (e.g. CI that is skewed indicates a trend in the hypothesized direction) for clinically important treatment differences within the limits (Loftus & Masson, 1994; Wykes, Parr, & Landau, 1999). The purpose was to explore the likely ranges for intervention effects at 12 weeks by assessing confidence intervals of mean difference scores. The mean difference and upper and lower limits of the 95% confidence intervals were computed from ANCOVA estimated marginal means (e.g. means adjusted for the effect of the covariate).

Hypothesis 2: Will adherence to the protocol lead to improvements in insight and symptoms?

The second aim explored the hypothesis that increased self-monitoring, as measured by higher levels of adherence to the ClinTouch protocol, led to higher levels of clinical and cognitive insight as measured by improvement in the BCIS, SUMD-A and the CHOICE. Pearson partial correlation coefficients were conducted using the following measures of adherence:

(i) Total number of entries completed over the 12 weeks
(ii) number of days when at least one entry was completed
(iii) Number of entries during the last week of the protocol (week 12)
(iv) number of entries during the first week of the protocol (week 1)

The change in scores on insight variables, PANSS variables and GAF score were correlated with the above measures of adherence. Change scores were calculated as week 12 score minus week 0 score. For example, a negative change score for the PANSS and SUMD-A (e.g. Week 12 score (10) minus Week 0 score (15) = -5) indicates improvement. As these methods are exploratory, all of the statistics and p-values are presented for the main adherence measure of interest, 'total entries completed over the 12 weeks' (see table 5). Additionally, only the significant correlations and trends for notable correlations ($p<.15$ and r value > .300) are presented for the other three measures of adherence (see table 7). This analysis is conducted on the experimental group only.

Insight in adherent and non-adherent participants

A supplementary analysis was completed to examine any changes in insight or symptoms for adherent and non–adherent participants in the experimental group. 'Adherent' refers to those participants who completed at least 33% of entries (N=14); 'non-adherent' participants (N=6) did not reach this threshold (Palmier-Claus et al., 2012). Adherent and non-adherent participants were compared for baseline differences using Welch's t-test statistic for unequal sample sizes. Partial correlations controlling for baseline scores, between the adherence measures listed above and change in insight and symptom variables were examined separately for each group. It was predicted that those in the adherent group would have stronger correlations between adherence measures and change to improved insight.

Finally, participants were categorised into three different adherence groups; 1) low: <33% of entries completed, N=6 2) mid: >33 but <66% of entries completed, N=9 and 3) high: >67% of entries completed, N=5. Welch's t-tests for unequal sample size were conducted on change scores (week 12 minus week 0 scores) and week 12 scores for all insight and symptoms measures to compare the three different groups in terms of change in insight/symptoms and week 12 insight/symptoms. It was predicted that those in the high adherent group would have the most improved insight and the highest insight scores.

Hypothesis 3 Will improved insight lead to change in symptoms and functioning?
In addition to examining any potential change in insight measures we also predicted that the experimental group would show an improvement in symptoms and functioning at week 12 as a by-product of self-monitoring, when compared to the TAU group. ANCOVA's were performed on symptoms and functioning variables at week 12, comparing the experimental and TAU groups. It was predicted by Ampalam, Deepthi, & Vadaparty, (2012) that improved insight may lead to a worsening of depression symptoms. Pearson's partial correlations controlling for baseline PANSS positive symptom or depression symptoms (PANSS general item 6) were performed on the change scores (week 12 minus week 0) of insight (SUMD-A sumtotal or BCIS composite) and PANSS PS or depression variables, to examine if change in insight was related to change in symptoms. Two specific hypothesis were examined:

1) Improved insight will correlate with fewer symptoms of delusions and hallucinations as measured by the change in the PANSS positive symptom scale.
2) Improved insight will correlate with higher symptoms of depression as measured by change in the general item 6 on the PANSS.

2.5 Procedure

Questionnaire measures were assessed at 0 weeks (baseline) and 12 weeks (outcome). After the baseline assessment, participants were randomized or allocated to the experimental or TAU group. In the experimental group they received the ClinTouch mobile app and detailed instructions on the ClinTouch mobile procedure (see Appendix 3). Participants in the experimental group received weekly follow-up phone calls to provide technical support and to discuss any questions or difficulties.

2.5.1 ClinTouch Procedure

Participants chose whether to use a loaned ClinTouch Smartphone with the application already installed, or their own smart phone. Samsung Galaxy smartphones and the Vodafone UK mobile phone service was used to supply the SIM cards and monthly Top up credit. When the participant preferred their own phone, researcher CK downloaded the application to the service users own phone and ensured that it was functioning correctly at the baseline testing session. When the ClinTouch mobile app beeped the participant was alerted to respond to 18 questions that covered positive psychotic symptoms, anxiety and mood. This took about two minutes to complete. Each participant received four alerts a day for 12 consecutive weeks. Please find attached a list of the questions that the participants will be prompted to answer (Appendix 4).

Development of ClinTouch questions: These questions have been extensively piloted and assessed (Palmier-Claus et al., 2012; Ainsworth et al., 2013). Briefly, the 18 questions were developed based on the PANSS and two items of the Calgary Depression scale (Addington, Addington, & Schissel, 1990). Participants were asked to indicate on a scale from 1-7 how much they agreed with each question. To reduce the

amount of time required to complete the questionnaire the questions were split into two question sets that were presented alternatively.

2.5.2 Participant Payment

Participants in the experimental and TAU groups received payment for each testing session (baseline session £15 and week 12 session £20). If they were allocated to the experimental group, they received a prepaid mobile phone credit (£30) for 3 months. If they agreed to take part in the qualitative interview they were paid an additional £5.

2.6 Qualitative Methods

A brief structured qualitative interview with open-ended questions was used to provide additional insights into the main hypotheses; 1) *Will self-monitoring improve insight measures at week 12*?
and 2) *Will adherence to the protocol lead to improvements in insight and symptoms?* (Morgan, 1998). The data were analysed following the principles of Framework analysis, supported by an approach known as Iterative Categorization (Neale, 2016). Framework analysis is a transparent and systematic technique that is particularly suitable for qualitative data that have been collected with a clear structure; for example, a predetermined sample with a-priori research questions (Neale, 2016; Palmier-Claus et al., 2013). Framework consists of several systematic stages including 1) coding 2) applying an analytical framework 3) charting data into the framework matrix and 4) interpreting the data (Gale, Heath, Cameron, Rashid, & Redwood, 2013). The steps for data coding and analysis are outlined in detail below.

2.6.1 Structured Interview

The structured interview topic guide covered the following three topics: self-reported change in clinical insight (awareness of a mental health problem), cognitive insight (awareness of thoughts and cognitions pertaining to mental health problem), and metacognitive regulation (the process of self-monitoring and reflection of one's own thinking). Two additional topics were also included in the interview schedule (support

from care-coordinator and additional metacognitive knowledge) however analysis of these questions is beyond the scope of this project. For each topic, the researcher asked a series of open-ended questions, using prompts and probes. The interviewer also prompted throughout for moments of self-understanding or understanding the connection between mood, symptoms and behavior connected to self-monitoring using the Clintouch app (see Appendix 5 for the topic guide).

2.6.2 Data Collection and recording

All 15 participants who completed the experimental mobile phone intervention between May and December 2015 were approached to take part in the qualitative interview. During the baseline assessment at week 0, the nature of the qualitative interview was explained and participants were asked if they would like to take part. Written information and a consent form were then provided. All of the participants consented to complete the interview and attended the subsequent interview session during the outcome assessment at week 12. Interviews took place at a community mental health team base. The interviews were audio-recorded. When presenting the data, quotations will be used with an anonymous participant code (e.g Participant 1).

2.6.3 Data coding

Due to the nature of the data (i.e. clearly structured interviews) it was not necessary to use specialist software to transcribe or analyze the data. The audio recordings of the interviews were not transcribed verbatim but were summarized in brief, descriptive text. Researcher CK summarized the audio recordings into shorter descriptive phrases that retained the content of the participants' narrative, using an excel spreadsheet. Participants' responses to each interview question were entered into a framework matrix; i.e. a Microsoft excel (2010) spreadsheet was designed whereby each column represented a question from the interview topic guide and each row represented a participant case. This method of coding the data according to a predetermined structure (the interview topic guide) is known as deductive coding. During the deductive coding process new, inductive codes were noted as they arose from the coding process. Inductive codes, for example, 'questioning experiences' and

'confusion' where added to the coding structure as additional columns to the spreadsheet. Exemplar quotes were noted with a *Q*. Appendix 6 provides an overview of the methodological strategy used including examples of the stages of data coding and data analysis.

2.6.4 Data Analysis

Once the coding of the data was complete the data were analyzed through a process of iterative categorization. This is a transparent and systematic analytical technique that can be used alongside many different qualitative research methods including Framework (Neale 2016). Iterative categorization has two main assumptions; 1) that the study has a clear aim and objective 2) that the interview topic guide or protocol used for data gathering was designed based on theoretically relevant literature that informed the aims and objectives of the study. A Microsoft word file for each of the interview questions was created. The summaries of the participants' responses to each question were analyzed and categorized into different themes and subthemes. These themes emerged from the participant responses. Additionally, some simple numeric data was produced, such as frequency of a yes or no response, in order to complement the quantitative questionnaire data.

2.6.5 Participants

13 males and 2 females completed the interview. The median age of participants was 26 years. The majority of participants indicated that they were from a minority ethnic group (80%). The majority (73%) were unemployed and single (93%).

TABLE 2 DEMOGRAPHIC CHARACTERISTICS OF INCLUDED PARTICIPANTS

	Interviewees (n=15)
Gender: males % (n)	**86 (13)**
Age: median (range)	**26 (20-29)**
Ethnic minority: % (n)	**80 (12)**
Years of education: median (range)	**13 (9-17)**
Accommodation, Local housing authority: % (n)	**40 (6)**
Relationship status, Single: % (n)	**93 (14)**
Unemployed: % (n)	**73 (11)**
Number of psychiatric admissions to hospital: median (range)	**1 (0-3)**

3. Results

Demographic and clinical characteristics of participants are presented in Table 3. 81 participants were approached, 37 declined, 44 consented to participate in the study. 22 participants were recruited to the experimental group and 22 were recruited to the TAU group. After consenting to participate four participants dropped out of the study (lost mobile phone N=1, mobile phone beep was too frequent N=1, inpatient admission N=1, refused to complete week 12 assessment N= 1). Please see figure 1 for a CONSORT diagram overview. There were no predictors of drop-out based on baseline PANSS, GAF, SUMD-A, BCIS and the CHOICE scores. Visual inspection of the data also confirmed no notable clinically relevant differences. In order to provide a descriptive overview of the data, (as outlined by Lancaster et al., 2004 for exploratory studies), means and standard deviations of insight, symptoms and functioning measures are presented in Table 4 along with confidence intervals of the mean difference between the experimental group and TAU group for all week 12 measures.

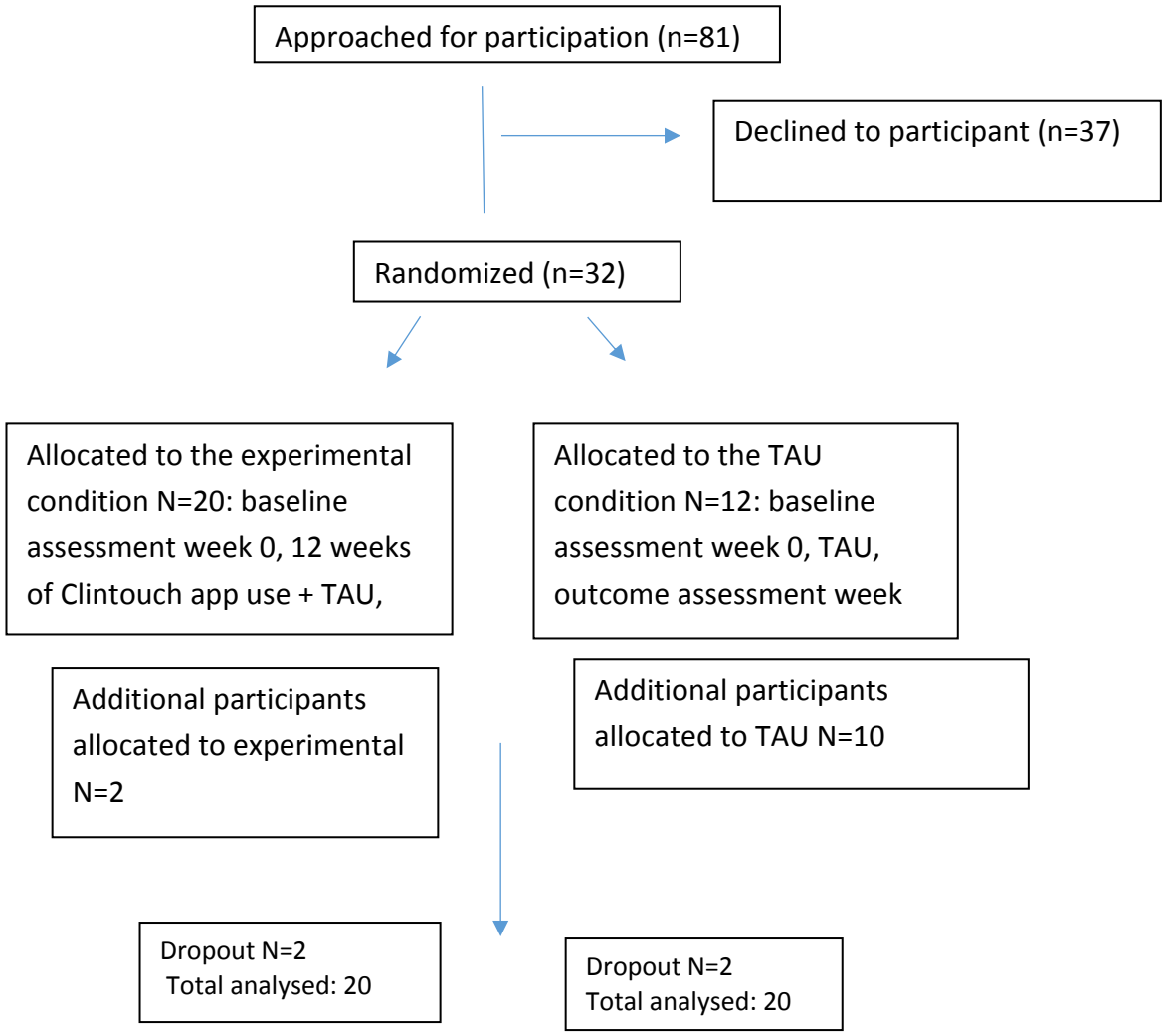

FIGURE 1 CONSORT DIAGRAM OF RANDOMIZATION AND ALLOCATION OF PARTICIPANTS

TABLE 3 DEMOGRAPHIC CHARACTERISTICS OF INCLUDED PARTICIPANTS

	Experimental Group (n=20)	***TAU Group (n=20)***
Gender: males % (n)	**75 (15)**	**55 (11)**
Age: median (range)	**26 (20-35)**	**27 (19-40)**
Ethnic minority: % (n)	**75 (15)**	**80 (16)**
Years of education: median (range)	**13 (9-17)**	**14 (10-18)**
Accommodation, Local housing authority: % (n)	**45 (9)**	**35 (7)**
Relationship status, Single: % (n)	**90 (18)**	**90 (18)**
Unemployed: % (n)	**75 (15)**	**75 (15)**
Number of psychiatric admissions to hospital: median (range)	**1 (0-3)**	**1 (0-3)**

3.1 Group matching

Independent samples t-tests on all PANSS, GAF and SUMD-A sum baseline scores indicated that the experimental and TAU groups were well balanced (PANSS positive (p=.387), negative (p=.371), general (p=.735) and total (p=.810) scales; GAF score (p=.814) and SUMD-A sum total scores (p=.123)).

3.2 Hypothesis 1: Will self-monitoring improve insight measures at week 12?

Table 4 shows the mean and standard deviations of the key metacognitive outcome measures and the symptom and functioning measures. 95% confidence intervals for the adjusted mean difference (controlling for baseline scores) between week 12 scores are also presented.

TABLE 4 MEANS, STANDARD DEVIATIONS (SD) FOR THE MAIN OUTCOME VARIABLES. CONFIDENCE INTERVALS (CI) ARE CALCULATED FOR THE MEAN DIFFERENCE BETWEEN GROUPS AT WEEK 12 ADJUSTED FOR BASELINE SCORES; [1] INDICATES TREND FOR SIGNIFICANCE IN THE HYPOTHESIZED DIRECTION, * INDICATES SIGNIFICANT ANCOVA

Measure	Baseline Scores: mean (SD)		Week 12 Scores: mean (SD)		
	Experimental Group	*TAU*	*Experimental Group*	*TAU*	*Adjusted Mean difference (MD), 95% CI*
SUMD-A total	12.4 (4.37)	14.9 (5.59)	12.2 (2.76)	15.75 (5.90)	MD: -2.22 95% CI: -4.73 to .298[1]
SUMD-A MD index	4.05 (1.39)	5.05 (1.9)	3.8 (1.19)	5.20 (2.1)	MD:-.748, 95% CI: -1.653 to .157[1]
SUMD-A PS index	3.85 (1.78)	4.70 (2.45)	3.35 (1.42)	4.55 (2.45)	MD: -.863, 95% CI: -2.069 to .344
SUMD-A NS index	4.50 (2.35)	5.15 (2.43)	5.05 (2.09)	6.00 (2.53)	MD:-.692, 95% CI: -2.081 to .697
BCIS Composite	6.75 (3.72)	4.80 (6.5)	7.0 (4.5)	3.75 (5.32)	MD:2.08 95% CI: -.44 to 4.61[1]
BCIS Self Reflexivity	12.65 (4.09)	12.9(4.67)	13.75 (4.39)	12.15 (4.53)	MD: 1.733, 95% CI:-.733 to 4.199
BCIS Self certainty	5.9 (2.73)	8.10 (2.93)	6.75 (2.38)	8.40 (3.16)	MD:-.313, 95% CI: -1.85 to 1.232
CHOICE Severity	6.59 (1.64)	5.64 (1.83)	6.38 (1.73)	6.11 (1.74)	MD:-.417, 95% CI: -1.22 to .390
CHOICE Satisfaction	5.95 (2.07)	5.41 (2.53)	5.80 (2.2)	5.39 (2.22)	MD:-.019, 95% CI: -.862 to .824
PANSS total	74.45 (15.38)	75.65 (15.99)	64.65 (14.60)	70.05 (18.78)	MD:-4.491, 95% CI:-12.2 to 3.24
Positive Scale	19.05(4.72)	17.70 (5.02)	15.40* (4.53)	17.00* (5.58)	MD:-2.55, 95% CI: -5.0 to -.088
Negative Scale	17.50 (5.37)	19.10 (5.79)	16.25 (4.65)	17.95 (6.13)	MD:-.497, 95% CI: -2.77 to 1.77
General Scale	37.90 (8.66)	38.85 (8.94)	33.0 (7.84)	35.1 (9.21)	MD:-1.55, 95% CI: -6.05 to 2.94
GAF	46.85 (13.49)	45.95 (10.35)	53.15 (12.86)	54.3 (16.49)	MD: -1.85, 95% CI:-9.26 to 5.551

3.2.1 BCIS: Cognitive Insight

The ANCOVA analyses revealed no significant differences between groups on the self-reflexivity subscale (F(1,37)=2.02, p=.163) or self-certainty subscale (F(1,37)=.169,

p=.684)[8]. An ANCOVA controlling for baseline BCIS composite score revealed no significant differences between groups at week 12. However, the confidence intervals indicated a trend for significance (F(1,39) = 2.806, p = .102, MD:2.08, 95% CI: -.44 to 4.61) whereby the experimental group had higher insight at week 12 than the TAU group (means: experimental 7.00, TAU 3.75) after controlling for baseline.

3.2.2 SUMD-A: Clinical Insight

The results from ANCOVAs on all three subscales at week 12 variables were non-significant; positive symptoms subscale (F(1,37)=2.099, p=.156), and negative symptom subscale (F(1,37) 1.018, p=.320). However, there was a trend for significance in the hypothesized direction on the SUMD-A medical disorder subscale (F(1,37)=2.808, p=.102; MD:-.748, 95% CI: -1.653 to .157), with lower scores of unawareness (meaning greater insight) for the experimental group (means: experimental 3.8, TAU 5.20).

For the SUMD-A sum total, there was a trend for difference between groups at week 12 with an ANCOVA approaching significance (F(1,39)= 3.192, p =.082; MD: -2.22 95% CI: -4.73 to .298) whereby the experimental group had lower scores of unawareness (meaning greater insight) at week 12 (means: experimental 12.2, TAU 15.7).

3.2.3 CHOICE: Self-reported awareness of coping and recovery

The ANCOVA revealed no significant differences in week 12 scores between groups on the CHOICE satisfaction subscale (F(1,37)= .002, p=.964) or the CHOICE severity subscale (F(1,37)= 1.096, p=.302).

In summary, there were no statistically significant differences between the groups on these measures of insight at week 12. However, there are trends in the hypothesized direction indicative of improved insight for the experimental group on the BCIS composite scale (p=.102), the SUMD-A mental disorder subscale (p=.102) and the SUMD-A sumtotal scale (p=.082).

[8] Figures showing non-significant effects can be found in Appendix 7: Results

3.3 Hypothesis 2: Will adherence to the protocol lead to improvements in insight and symptoms?

Data for the main adherence variable of interest, *total entries*, are presented here to provide an overview of the effects.

3.3.1 Adherence Measure 1: Total Entries over 12 weeks

All partial correlations, controlling for baseline scores, were non-significant for total number of entries and all insight measures. There was a trend for a significant positive partial correlation between total number of entries and SUMD-A sum total change score (r=.405, p=.085) and SUMD-A negative scale change score (r=.428, p=.067). This indicates that the higher the total entries, the more unawareness increased – i.e. awareness worsened. This is mirrored by the a weak correlation (r>.300) between number of entries and CHOICE subscales indicating that the higher the number of entries, the CHOICE scores declined indicating a worsening of scores, however this is non-significant.

TABLE 5 PARTIAL CORRELATIONS CONTROLLING FOR BASELINE SCORES BETWEEN CHANGE IN INSIGHT MEASURES AND TOTAL ENTRIES COMPLETED. [1]INDICATES POTENTIAL TREND.

Measure	Partial correlation on change score
SUMD-A: sum total	r=.405, p=.085[1]
SUMD-A:NS	r=.428, p=.067[1]
CHOICE: Severity	r=.-.317, p=.186[1]
CHOICE Satisfaction	r=.-.347, p=.115[1]

In addition, although all partial correlations were non-significant between total entries and change in symptoms or functioning, there is a notable correlation between number of entries and the PANSS positive scale and PANSS negative scale (r >.300); as entries increase, symptoms increase, (i.e. symptoms get worse) however, this is non-significant. There is also a negative correlation between GAF and number of entries (>.-300), indicating that as entries increased GAF score decreased meaning a worsening in functioning, however this is also non-significant.

TABLE 6 PARTIAL CORRELATIONS BETWEEN CHANGE IN SYMPTOMS/FUNCTIONING AND TOTAL ENTRIES COMPLETED, [1]INDICATES NOTABLE TRENDS

Measure	Partial Correlation on change score
PANSS: Positive Scale	r=.369, p=.120[1]
PANSS: Negative Scale	r=.377, p=.112[1]

In terms of the additional three adherence measures (number of entries for week 1, number of entries for week 12 and number of days adherent), the significant and nearly significant (i.e. with a significance level <.15 and a correlation coefficient > .300) partial correlations are presented in table 7. All of the other correlations between insight and symptom variables were non-significant.

TABLE 7 NOTABLE PARTIAL CORRELATIONS FOR ADDITIONAL MEASURES OF ADHERENCE: * STATISTICALLY SIGNIFICANT

Additional Adherence Measures	Partial Correlations on change scores
Week 1	
SUMD-A NS	r= .420, p=.073
PANSS Total	r=.417, p=.076
PANSS PS	r= .452, p=.053
PANSS NS	r=.674, p=.002*
Week 12	
SUMD-A total	r=.600, p=.007*
SUMD-A NS	r=.439, p=.060
# of days adherent	
SUMD-A NS	r=.425, p=.069
GAF	r=-.405, p=.085

All of the partial correlations suggested that the higher the number of entries completed the greater decline or worsening of insight and symptoms. There was a statistically significant positive partial correlation between number of entries at week 1 and PANSS negative subscale score, indicating that the more entries at week 1, the higher the symptoms. There were similar trends for the PANSS total, PANSS positive scale and SUMD-A negative scale; the more entries at week one the worse the symptoms. The number of entries at week 12 significantly positively correlated with SUMD-A sum total and were nearly significant with SUMD negative scale indicating that as entries increased unawareness increased (i.e. worse insight). Finally, the

number of days adherent was nearly significantly correlated with the SUMD-A negative scale indicating that as days increased, unawareness of negative symptoms increased. The number of days adherent shows a trend for negative correlation with the GAF week 12 score, indicating that as number of days increased, GAF score decreased or became worse. In summary, the partial correlations reveal that if there is a correlation, this is in the direction of the negative effect of completion rate and score at week 12; as the number of entries completed increases, symptoms and insight becomes worse.

3.3.2 Insight in adherent and non-adherent participants

We explored the hypothesis that those in the adherent group[9] would have correlations suggesting a positive effect between adherence and change in insight. Baseline comparisons (Welch's t-test statistic) found no significant differences between adherent (n=14) and non-adherent (n=6) groups on baseline symptom (PANSS PS: p=.732, PANSS NS: p=1.000, PANSS GS: p=.562, PANSS total: p=.664, GAF: p=.805) and baseline insight variable scores (BCIS composite: p=.728, SUMD sumtotal: p=.412, CHOICE satisfaction: p=.264, CHOICE severity: p=.473).

Adherent group

In terms of the adherent group there was a significant positive partial correlation between number of entries at week 12 and change in SUMD-A sum total (r=.565, p=.044) and a nearly significant positive partial correlation between number of entries at week 12 and change in SUMD-A PS (r=.485, p=.093). This indicates that as entries increased, lack of insight also increased (i.e. awareness worsened). There was also a nearly significant correlation between the BCIS self-reflexivity scale and the number of days adherent (r=.485, p=.093). This indicates that as adherence increased, one variable of insight, self-reflexivity increased (i.e. self-reflexivity improved). There were no other significant correlations for the adherent group.

[9] Completed >33% of entries

Non-adherent group

For the non-adherent group there was a significant partial correlation between week 1 entries and change in BCIS self-reflexivity subscale (r=.941, p=.017) indicating that at this early time point, as adherence increased, insight increased (i.e. improved). There was a nearly significant negative correlation between number of days adherent and change in the BCIS self-reflexivity scale (r=-.834, p=.079) indicating that as adherence increased insight decreased (i.e. worsened) at this later time point. There was one nearly significant correlation between week 1 entries and change in PANSS PS (r=.851, p=.068) and a significant correlation between week 1 entries and change in PANSS ns scales (r=.894, p=.041) indicating that as entries increased symptoms worsened.

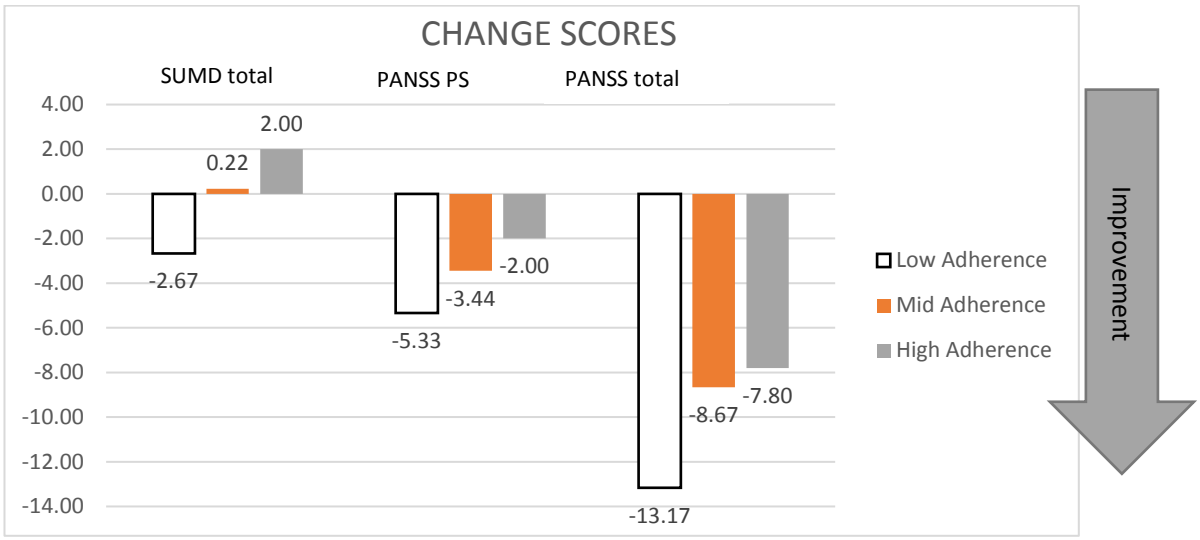

FIGURE 2 CHANGE IN SCORES ON THE SUMD-A TOTAL CHANGE, PANSS PS CHANGE AND PANSS TOTAL CHANGE FOR THE THREE ADHERENCE GROUPS. NEGATIVE CHANGE SCORE INDICATES THAT THE OUTCOME SCORE IS LOWER (BETTER) THAN THE BASELINE SCORE

When the 20 experimental group participants are grouped into three categories based on levels of adherence (low n=6, mid n=9, high n=5) visual inspection of the change scores suggests that the mid and low adherence groups have the highest levels of insight at week 12, and better symptoms scores at week 12 (see figure 2). This fits with other analyses reported above; low adherence groups have higher insight and fewer symptoms compared to the high adherence group. However, statistical testing found no statistically significant differences between the three groups. Overall this could indicate that those who use the app regularly experience a worsening of symptoms,

whereas those who benefit from improved insight at week 1 no longer make use of the app.

3.4 Hypothesis 3: Will improved insight lead to change in symptoms and Functioning?

A secondary analysis was conducted to examine any differences between the experimental and TAU groups in symptoms and functioning at week 12.

3.4.1 Symptoms: PANSS subscales

An ANCOVA controlling for baseline scores revealed no significant differences between groups on the PANSS total score (F(1,37)=1.382, p=.247), the PANSS negative symptom scale (F(1,37)=.169, p=.660) and the PANSS general symptom scale (F(1,37)=.491, p=.488) at week 12. However, there was a significant difference between groups at week 12 on the PANSS positive subscale (F (1,37)=4.406, p=.043) whereby the experimental group had improved symptoms (means: experimental 15.4, control 17).

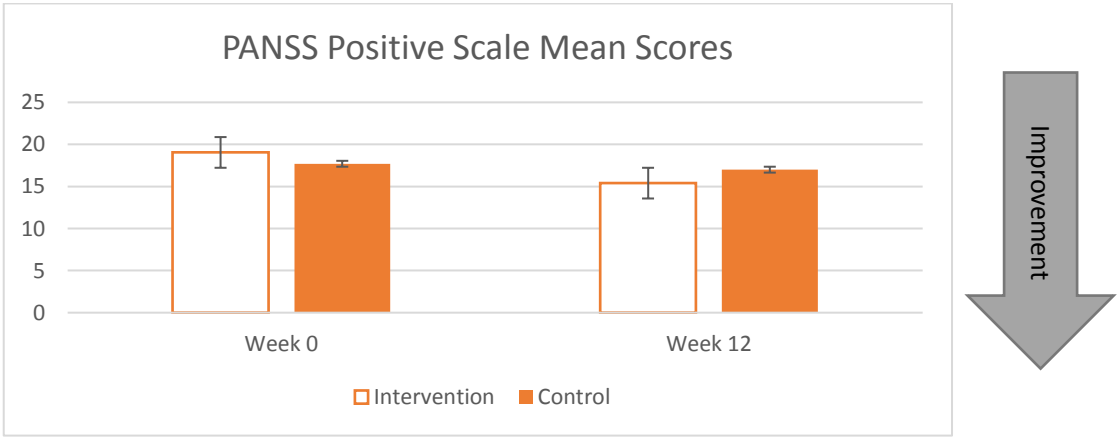

FIGURE 3 MEAN SCORES AND STANDARD ERRORS AT BASELINE AND WEEK 12 ON THE PANSS POSITIVE SYMPTOM SUBSCALE

3.4.2 Global Assessment of functioning (GAF)

An ANCOVA revealed no significant differences between groups at week 12 (F(1,37)= .258, p=.615).

3.4.3 Partial Correlations between change in insight and symptoms

There was no evidence that improvement in insight leads to improved PANSS positive symptoms (i.e. less delusions and hallucinations). The partial correlation between SUMD-A sum total change score and PANSS PS change score was non-significant (r= .289, p=.230), controlling for baseline PANSS positive symptoms. The partial correlation between BCIS composite change and PANSS PS change scores was also non-significant (r=.326, p=.173), however this is suggestive of a weak correlation whereby as BCIS insight improves PANSS PS symptoms become worse.

To examine the hypothesis that improved insight may lead to increased symptoms of depression as measured by general item 6 on the PANSS, there were no significant partial correlations between change in SUMD-A sum total insight and change in PANSS G6 score (r=.132, p=.589) (controlling for baseline PANSS G6 score). There was no partial correlation between BCIS change in composite score and change in depression score (r=.380, p=.109) (controlling for baseline PANSS G6 score), however there is a weak correlation indicating that as insight improves depression scores become worse.

In summary the quantitative results find minimal statistically significant effects in support of the hypothesis that taking part in monitoring via ClinTouch will benefit insight. However, the statistically significant ANCOVA (PANSS PS scores improved for the experimental group), and the trends for confidence intervals are skewed in the hypothesized direction of improved insight for the experimental group (SUMD total, MD index, and BCIS composite score). The analysis of adherence provides some interesting insight into how participants used the app. The correlational data suggests that those who use the app the most have an increase in PANSS PS and NS symptoms during the first week and at the end of 12 weeks. Higher total entries, greater number of days adherent, and higher number of week 12 entries are related to worse awareness of mental disorder as rated by the SUMD-A. Those who use the app regularly may decline in levels of insight and experience worse symptoms. There was one correlation that indicated a positive effect on insight; as adherence increased self-reflexivity as measured by the BCIS improved.

3.5 Qualitative Analysis

The below is a summary of the findings from the interview data. The complete iterative categorization process including the coding and theme identification for each question can be found in Appendix 8.

3.5.1 Analysis of Clinical insight

In order to examine clinical insight at week 12, the questions 1.1 '*Do you believe you have a mental health problem?*' and sub question '*What is your main problem or difficulty at the moment?*' were analysed. The majority of participants confirmed that they had a mental health disorder and that this was called either schizophrenia or psychosis (N=9). For example Participant 2 said '*Yes, at the moment it is fairly stable, I think it is psychosis because of the things that I experience'.* Of these participants, most identified a combination of symptoms including paranoia, hearing voices, stress and depression. Some participants (N=4) reported that currently their main difficulty was not necessarily related to schizophrenia or psychosis. For example Participant 3 reported '*I don't suffer from a mental health difficulty, just trauma from my life just all came on top of me'* and Participant 5 '*When I have a lot of stress I end up making things up as I go along, overwhelming feelings that I want to be special*'

Participants 4, 8, and 10 identified that their way of thinking was different from others, for example Participant 8: *'My thinking is not quite right, not the same as other people'*

Finally, two participants reported that they felt they did not have a mental health difficulty and instead reported that they thought they were addicted to medication or that they had no difficulty at all, for example, Participant 12: '*I don't really know 100%, I am addicted to medication so I need to keep taking it*'. Overall the majority (n=9) of participants indicated that they believed they had a mental health problem related to psychosis or schizophrenia. This corresponds to question 1 of the clinician rated SUMD-A questionnaire that rated the majority of individuals (10 out of the N=15 interviewed) as having awareness of mental health disorder. This indicates that the interview and questionnaire data are complementary and that the majority of participants had clinical insight post self-monitoring. The qualitative methods also

expand on the quantitative findings by providing a broader and more diverse narrative of service users understanding and experience. For example, not only do many service users understand that they have a mental health disorder but different service users attributed this to common (e.g. hearing voices) and uncommon (e.g. thinking differently) symptoms.

3.5.2 Analysis of Cognitive Insight

In order examine cognitive insight at week 12, participants were asked 2.1 *'After monitoring your mood, symptoms and behaviour do you have any alternative understanding of your unusual experiences (or negative symptoms, or social withdrawal or paranoia (when applicable)'* plus the sub-question *'After self-monitoring with the app are you aware of any errors in your thinking or interpretation of experiences?'*

In response to this question several participants made statements and responses that indicated an alternative or emerging new understanding of their experiences. Correspondingly the responses were categorized into two themes*; 1) developed a new understanding of self or experiences* and *2) an emerging understanding*.

In terms of *developed a new understanding of self or experiences*, three subthemes could be identified. First, three participants, 4,7 and 8 reported that they had a clearer understanding that their experiences were in their 'mind and not in reality', for example participant 8 reported *'I just realized that it was my imagination, sometimes I would see like a ghost'* or participant 4 '*When it mentioned voices I would click about a 2 meaning not at all but when it was thoughts I would click higher, so I would start to distinguish it in a way'.* Second, participants 3 and 6 reported a 'new understanding of their symptoms'. They understood that it was part of a mental health disorder. For example Participant 3 '*The app helped to understand that paranoia was a symptom and it is something you are going through and not reality*' or Participant 6 'Previously I was getting into problems with people and thinking that they were going to harm me, this was the symptoms of psychosis, I understand this better now, as I got the phone I understood that I wasn't answering the psychosis questions'. Third, participants 13 and

1 reported a new 'understanding of their experiences in everyday life', Participant 13 *'When it asked, how do you see yourself compared to the average person, I felt normal'* and Participant 1 *'It helped me to understand that these experiences in the past weren't real'.*

Aside from developing a new or alternative understanding several participants reported what could be considered an emerging understanding. For example, increased noticing of connections between how they were feeling, what they were doing and their symptoms. For example, participant 12 noted '*it was an unusual experience every time there was a new feeling and emotions, I try to understand it and figure it out*' or Participant 11 *'At the moment I think that if I get too stressed then I start to get more symptoms of my mental health condition'.* Although these reports did not necessarily indicate a new or different understanding of experiences it suggests that participants were questioning and developing an emerging alternative understanding. For example, participant 2 reported *'Does that mean that I don't have psychosis, if I don't experience one of the main symptoms? Or maybe it is a good sign that this is recovery'* and Participant 15 '*When I was paranoid at work I just believed them to be true, but I wasn't 100% sure, after speaking to care coordinator she explained that I don't have any evidence to back up these thoughts, so then I decided that they probably weren't true'*.

Finally, some participants found that self-monitoring did not lead to any additional knowledge or understanding of patterns in their experiences. Two participants, 7 and 2, reported increased confusion, for example Participant 2 '*I wouldn't say so, more confusion about symptoms, questioning if I have psychoses'* and Participant 7 '*I didn't have an understanding and I don't know why, At first I thought it was just part of the anxiety, but the voices have to do with psychosis as well, it was confusing at first*'. Other participants noted that the app did not help them learn anything new or to notice patterns, for example, Participant 11 '*I wouldn't say so, I did glance at the charts once, my symptoms did seem to be going up and down but most of the time I wasn't really monitoring the charts*'.

3.5.3 Analysis of self-monitoring/metacognitive regulation

In order to examine the relationship between adherence to the self-monitoring protocol and insight the following interview question was analysed; (1) Question 3.1 *'Is it important/helpful to self-monitor? For example, to keep track of specific patterns or connections between mood, behaviour and symptoms?'* The majority of participants identified that self-monitoring with the mobile app was helpful (n=13) and their responses indicated four themes that qualified the importance or helpfulness of the app. Firstly, the app allowed 'time for reflection'. The majority of participants (n=13) recognised the positive experience of reflecting on their thoughts and experiences. This took the form of three subthemes or approaches including:

- Five participants reported 'Questioning and speaking to themselves': for example, participant 14 reported *'A lot of people don't do that, a lot of people are too busy, they ask other people, but don't think to themselves how am I doing, made me consider my own feelings instead of everyone else's, noticed that I was feeling quite good the majority of the time'* and Participant 5 *'Ask myself how I feel once in a while'*
- Four participants reported that they began to notice 'changes from day to day', for example participant 13 *'Yes, you could see from day to day how things were going and how things were changing'* and participant *15 'It helped me see that things aren't always good, notice more the changes that I experience more in my thoughts, see that sometimes I am more paranoid and sometimes more optimistic'*

Four participants reported that reflection and thinking led to 'new learning or understanding' about their feelings, thoughts or experiences, for example participant 11 *'Understanding how I am feeling, and acknowledging how I am feeling at the time, good or bad and let me think about it more'* and participant 10 *'Step back and see life and notice that I was keeping track of my thoughts and mood'.*

Secondly, four participants reported a realization about themselves in terms of either understanding their symptoms or noticing recovery. For example, participant 13 reported '*Feeling worried nervous and anxious-realizing that there were sometimes*

when I was and sometimes when I wasn't, I wasn't as worried as I thought I would be'. Thirdly three participants reported that after monitoring they would like to 'do something' differently. For example, participant 4 reported that they are *'Trying to do more activities to do, but until I find something with a purpose it is hard to be happy'.* Others were less specific about what they might do, but felt that they should do something, for example, participant 11 reported *'[what] can I do to make me feel a bit better, because I am feeling a bit down'.* Fourthly one participant found that the app was helpful in terms of its ease of use and accessibility because of the personalized questions. For example, participant 1 said: *'do I trust other people? [those questions] were right on point, good questions to be answered by me, felt good because they were about me'*

Some participants also reported some uncertainty about the helpfulness of self-monitoring (n=7). Two participants reported that they found it difficult to integrate into everyday life for reasons such as it didn't always work, didn't have the time, and would need a little more practice to fully integrate it, for example participant 2 said '*Sort of helpful, it was slightly irritating, didn't always work*' and Participant 3 said '*Hard to adapt something new into your life, was good when I had it just didn't always have time*'. Two participants said that they did not necessarily learn anything new about themselves for example, participant 15 said '*Not sure if the app helped notice the connection between work and paranoia'.*

Finally, four participants reported that self-monitoring with the app had a negative impact on mood. Three participants identified that answering the questions sometimes made them feel upset, stressed or reminded them of their difficulties. For example, participant 6 said *'Started to get a bit stressed out with the phone, asking me silly questions, asking about killing myself'* and participant 8 *'It started making me feel like it was starting to pull me down, sometimes Id think what strategy goals could I do not to worry so much, pull myself together'*

In summary, the qualitative interviews not only complemented the questionnaire data, for example, the majority of participants demonstrating clinical insight (n=9) in their narratives in line with the questionnaires (awareness of a mental disorder) but it also added to and expanded on the findings. Analysis of the interview responses revealed that all 15 participants demonstrated some level of cognitive insight in the form of either a new understanding or emerging understanding of experiences. Finally, the majority of participants (n=13) identified that self-monitoring was helpful for reflecting and noticing patterns.

4. Discussion

4.1 Summary

In order to examine the hypothesis that intensive self-monitoring, using the ClinTouch mobile app, would prompt metacognitive regulation and lead to increased insight, a mixed methods design was used. The quantitative questionnaire data provided limited statistically significant evidence for improved insight on the questionnaire variables; however, there were trends for significance on the SUMD-A total, MD index and BCIS composite variables and statistical significance on the PANSS positive subscale indicating that the experimental group had improved scores at week 12. The qualitative data expands on the quantitative data by revealing themes and narratives of insight, such as new and emerging understanding of experiences, which are not captured by the questionnaire data. Notably when adherence to the intensive, prolonged app protocol is examined important negative effects are revealed; those who use the app regularly and for the longest appear to experience a worsening of insight and symptoms. This is the opposite of the predicted 'digital placebo effect'; people may indirectly experience deterioration in symptoms. Interestingly, as a whole, the group (across all adherence levels) shows trends for improvement in insight, potentially indicating that some people may experience a benefit in insight early and use the app less or stopping using it when they no longer find the app helpful or useful. There was a weak correlation indicating that as insight increased, positive and depressive symptoms increased. As people developed insight or awareness of symptoms they may have found it distressing or unhelpful to continue to monitor.

4.2 Does Self-monitoring produce significant effects?

Previous researchers have suggested a 'digital placebo effect' whereby mobile apps have the potential to indirectly improve symptoms in individuals with schizophrenia (Torous & Firth, 2016). Here we present one of the first examinations into the indirect effects of self-monitoring on metacognitive knowledge or insight.

TABLE 8 PRELIMINARY POSITIVE AND NEGATIVE EFFECTS OF SELF-MONITORING

Support for positive effects of self-monitoring
• **PANSS Positive symptom subscale significantly improved in the experimental group (p=.043)** • **Trends for significant improvement in the experimental group for:** ○ **SUMD-A total (p=.082)** ○ **MD index (p=.102)** ○ **BCIS composite scores (p=.102)** • **Positive partial correlation for adherent group: # of days adherent and improved self-reflexivity (BCIS) (p=.093), for non-adherent group positive partial correlation for week 1 entries and improved self-reflexivity (BCIS) (p=.017)** • **The majority of participants (n=13) reported a positive experience of self-monitoring in interviews**
Support for negative effects of self-monitoring
• **As total entries increase, there is an increase in unawareness (i.e worsening) (SUMD-A total p=.085, and SUMD-A NS, p=.067), higher week 12 entries corresponds to higher unawareness (p=.007)** • **Higher week 1 entries corresponds to higher symptoms (PANSS PS p=.053, NS p=.002), higher total entries corresponds to higher PANSS symptoms (PS p=.120, NS p=.112), and decrease in functioning (GAF p=.151)** • **Weak partial correlations: as insight increases (BCIS composite scale), positive PANSS symptoms worsen (p=.173) and depression symptoms worsen (p=.109)**

This study finds preliminary support for and against self-monitoring. Trends in the data suggest that insight may improve in the experimental group, however, this finding is not necessarily supported by the analysis of intensive, prolonged adherence to the protocol. Initially, high adherence at week 1 corresponds to an increase in PANSS symptoms, subsequently, at week 12, participants who adhere to the protocol the longest, experience less awareness. Overall, higher total entries correspond with increased unawareness, and decreased symptoms and functioning. There could be several reasons why there were limited significant or positive effects of self-monitoring on insight measures. The following will be discussed below: difficulty in measuring metacognitive change, negative effects of self-monitoring and lack of evidence for efficacy of smartphone interventions.

Above and beyond Metacognitive questionnaires

Metacognitive change may be difficult to detect because of the variability across the sample. There is substantial quantitative and qualitative variability in the insight profiles of participants (see Appendix 8 Section 8.2 Qualitative results). Some participants show improved insight in some measures and decline in insight on other measures and vice versa. The variability in insight could be explained by variability in the measures. The field is often criticized for not having a clear definition of insight, and many scales have been developed that attempt to capture disparate processes considered to be insight (Mintz et al., 2003). These questionnaires may measure different dimensions of insight that may change at different rates. For example, clinical insight may improve for some participants whereas cognitive insight has not yet developed to the same degree. Additionally insight tends to be examined through a medicalized lens, for example, the SUMD-A suggests that only those who acknowledge that they have a 'mental disorder' or 'illness', would be considered to have insight. From a psychological and service user perspective this is a limited model of insight. Individuals may not necessarily agree that they have mental disorder, but may acknowledge that trauma and stress contribute to their unusual experiences; equally this is insight into their thoughts and experiences. Recently Connell et al., (2015) found that from interviews of people with FEP, recovery meant developing an understanding of their experience in a way that allowed for growth and reconnection with familiar social roles. For some individuals it may be more helpful to think of their symptoms as a period of difficulty instead of a mental illness.

The qualitative interviews in this study provided valuable data on insight that expand on the questionnaire data. Codes from the qualitative interview data and quantitative scores on questionnaires are presented in Table 9. The data is presented for participants that were the two highest and lowest adherers to the app protocol to provide an overview of the variability in the data.

TABLE 9 VARIABILITY IN INSIGHT MEASURES AND QUALITATIVE REPORT. FOR THE COLUMNS LABELLED QUAL 1-3 IT IS INDICATED IF PARTICIPANTS DISCUSS NARRATIVES RELATED TO CLINICAL INSIGHT, COGNITIVE INSIGHT OR THE HELPFULNESS OF SELF-MONITORING. THE SCORES OF QUESTION ONE OF THE SUMD-A (1=AWARE, 2=SLIGHTLY AWARE/UNAWARE), % OF THE PROTOCOL COMPLETED, BCIS COMPOSITE SCORE AT WEEK 12 AND CHANGE IN BCIS COMPOSITE SCORE (POSITIVE INDICATES HIGHER/IMPROVED SCORE AT WEEK 12) ARE PRESENTED AS THE QUANTITATIVE DATA.

ID	Qual 1: Clinical Insight	Qual 2: Cognitive Insight	Qual 3:Self-monitoring helpful			BCIS Composite score Week 12	
2.00	Yes	Emerging	Sometimes	1.00	4.16	12.00	+3
10.00	Unrelated to psychosis	Emerging	Yes	2.00	3.86	6.00	-5
9.00	Yes	Emerging	No	2.00	96.4	8.00	+1
13.00	Yes	Developed	Yes	2.00	96.4	7.00	+3

As evident from Table 9 participants vary in terms of narratives indicative of clinical insight, cognitive insight and the helpfulness of self-monitoring. An example of '*emerging'* cognitive insight is found from participant 2: *'Does that mean that I don't have psychosis, if I don't experience one of the main symptoms? Or maybe it is a good sign that this is recovery'* And participant 9: *'It's just like a constant cycle, don't know when that cycle is going to end, just taking it one day at a time'* An example of having '*developed'* a new understanding is found in participant 13: *'but the question about hearing voices and trusting other people, I noticed I did trust other people, I hadn't really given it too much thought before, after doing the study did feel like could trust people more'*. Overall even though there is variability in the quantitative questionnaire data, for example, improvement and decline in the BCIS score at week 12, the change in BCIS score, and the score on the SUMD-A question 1, all of the participants reported narratives of either developed or emerging cognitive insight. The qualitative reports

provided valuable additional data on participants' experiences and the nature of insight. In the future it could be helpful to develop a quantitative questionnaire that rates participants on some of the themes related to insight that emerged from participants' narratives in this study. For example a measure that rates, not only participants developed insight (e.g. aware), but also narratives of emerging insight such as 'noticing connections between symptoms and mood', 'noticing patterns in symptoms' and beginning to 'question experiences' (see Appendix 8 for more potential themes and questions) could helpfully capture the variation and change in insight.

Negative effect of monitoring: increase in self-focus

The interview data also provided information on the potential unhelpfulness of self-monitoring. It should be noted that along with positive experiences such as noticing connections between symptoms and striving to improve their mood, many participants identified some unhelpful aspects to self-monitoring using the ClinTouch app. Themes that emerged included confusion arising from monitoring, difficulty integrating the app into everyday life, and a negative impact on mood (see appendix 8 for descriptive quotes). This is important to consider when designing future interventions; not all participants may find intensive, prolonged self-monitoring helpful, particularly in the short term. Participants reported that at times they found the app upsetting, particularly when they were asked about suicide or self-harm. This mirrors the weak correlational result whereby improved insight related to worse depression symptoms. A recent systematic review of smartphone interventions for schizophrenia found that none of the studies reported negative effects of the interventions, however, Ainsworth, Palmier-Claus, Machin, et al., (2013) found that one participant reported that her ruminative symptoms increased while using a mobile text intervention. Ben-Zeev, Kaiser, & Krzos, (2014) found that the less participants used a mobile intervention for psychosis (FOCUS), the greater improvement in their symptoms of depression. Wykes & Brown, (2016) proposed that self-monitoring interventions should be carefully managed because there is a risk that some participants may

experience increased self-focus and an unhelpful shift away from thinking of interactions with others and larger engagement with the world.

Lack of evidence for efficacy of smartphone interventions

Currently there is a lack of evidence for the efficacy of smartphone interventions for improving symptoms and functioning (Firth & Torous, 2015). A recent systematic review found five research studies examining the feasibility of smartphone apps for improving care for people with schizophrenia. Only one trial, Ben Zeev et al (2014), found preliminary efficacy for a mobile intervention, in terms of reductions of positive and negative symptoms and depression after participants used a mobile self-management intervention for managing medication, mood and social engagement for one month. None of the other smartphone apps identified in the above review specifically examined efficacy (Firth & Torous, 2015). This is an important area that requires further examination.

4.3 For whom is self-monitoring useful?

Wykes and Brown (2016) argue that intensive self-monitoring is only useful if it leads to improved understanding of the connections between thoughts, feelings and behaviours and/or promotes behaviour change. It could be that intensive self-monitoring is an effective and appropriate tool for some groups of participants and not for others. Interestingly in the current study, participants seemed to self-select into three groups; highly adherent, mid-range adherent and low adherent. The characteristics of the highly adherent participants indicate that those who adhered to the protocol for the duration of the 12 weeks may have experienced worse symptoms and insight. However, because there was an overall improvement in positive symptoms and trends for improved insight in the experimental group, across the different levels of adherence, it could be that monitoring had some positive effect on insight with some participants starting to notice their symptoms but perhaps needing a longer period of monitoring before insight could improve. Other participants may have gained some insight after a short period of self-monitoring, noticed their symptoms and then stopped monitoring.

TABLE 10 CHARACTERISTICS OF ADHERENT AND NON-ADHERENT PARTICIPANTS

Support for different service user profiles and use of the app
Intensive, prolonged use by service users • **Higher adherence at week 12 is correlated with worsening of insight** • **Number of days adherent correlates with worsening of SUMD-A for negative symptoms** • ***Specific to Adherent group:*** **as week 12 entries increased, unawareness scores increased (SUMD total and PS), however, insight was improving: BCIS self-reflexivity increased with number of days adherent**
Limited use by service users • **Higher GAF (higher functioning) correlated with less number of days adherent** • ***Specific to non-adherent group:*** **Higher week 1 entries and higher PANSS score; insight improved early: higher week 1 entries correlated with higher BCIS self-reflexivity (improved)**

Those who stop using the app early may experience an initial increase in symptoms as indicated by the correlation between higher symptoms and higher week one entries for non-adherent participants. It is also indicated that the non-adherent group may gain insight early, for example the correlation between high week 1 entries and higher BCIS self-reflexivity. Those who experience an initial gain insight may experience a worsening of symptoms and then stop using the app early. The correlation between increased insight and worse positive and depressive symptoms also supports the notion that some participants may have found it unhelpful to become aware of their difficulties.

A key consideration of the future of mobile self-monitoring apps will be to provide the service user with choice. It will be important to empower people to use the app for as long as they find it helpful and to be able to choose to stop when it is no longer helpful or has negative effects such as intensive self-focus (Wykes and Brown, 2016). On one hand, as a long-term recovery strategy, self-monitoring might be helpful, but it may be

an uncomfortable and time-consuming process. Self-discovery may lead to negative feelings at first, but it may be crucial for self-acceptance (Lysaker et al, 2005). On the other hand avoidance of awareness of current difficulties may be a particularly helpful strategy for others as it may increase rumination and self-deprecation.

4.4 Exploration of the Methodology

This study explored the use of the current methodology for detecting the indirect effects of self-monitoring using a mobile app on measures of insight and symptoms. Overall the current findings are not strong enough to suggest that further research using this methodology will be fruitful. Instead there are some preliminary findings that may inform different, but equally interesting and valuable research studies.

1) The use of a mixed methods approach provided complementary and expansive findings in terms of narratives indicating the improvement of insight. Future studies may consider continuing to use a mixed methods approach, particularly to capture insight. Although the current questionnaires are valid and informative measures they missed some valuable narratives of insight. Alternatively, the development of a questionnaire that includes assessment of participants' new insights into their experiences or awareness of emerging patterns may be helpful.

2) It was evident that many participants did not adhere fully to the intensive and prolonged self-monitoring 12-week protocol. A briefer intervention may provide similar yet more cost effective results. An analysis of a dose response to treatment, for example, the minimum amount of adherence required for an effect, could be useful.

3) The controlled study design comparing a 'blended' therapeutic approach, (i.e. an automated, mobile phone intervention is used alongside regular clinician support) with a mobile intervention without clinical support may provide interesting insights into factors that may influence adherence. It could be that the indirect effects of self-monitoring may need time and additional support from clinicians in order to translate into belief change.

4.5 Strengths and Limitations

One of the main limitations of this research project is that the experimental and TAU groups were treated differently. The experimental group received increased payment (e.g. £30 for mobile phone top-up) and this could have affected adherence. The experimental group also received a weekly supportive phone call from the researcher. This could have confounded the positive perception of the intervention for some participants. Additionally the ClinTouch mobile app was used in tandem with the CareLoop website intervention for staff. Staff may have engaged with the website intervention to different degrees; some not at all and some may have used the website to increased engagement with service users and to inform clinical practice. This may have impacted on service users' use of and experience of the ClinTouch mobile app. If the staff were responsive to the service users entries on the ClinTouch device this could have positively impacted on adherence. Unfortunately an analysis of this data was beyond the scope of this current work, however it should be carefully examined in the future.

This was an exploratory trial and not a randomized control trial, therefore although the majority of participants were randomized not all of the participants were. In addition, the exploratory trial is underpowered. This results in a less powerful design. Although assessments were conducted independently of the intervention, these were not blind.

Despite these limitations, this exploratory study provides the first examination of the potential indirect effects of self-monitoring on insight and symptoms. To capture the complexity of insight we have used three different insight measures along with measures of symptoms and functioning. In addition, we conducted comprehensive and expansive qualitative interviews that added greatly to the quantitative data. We also assessed the putative effect of self-monitoring over a prolonged and intensive 12-week period instead of just one week or month. Importantly we found that there may be some positive effects of self-monitoring in terms of trends for improved insight however the duration, intensity and content of the self-monitoring intervention should

be carefully considered as the overall there was a negative effect whereby higher completion rate led to worse symptoms and less awareness. The ‘digital placebo effect’ requires significant unpicking to determine the mechanisms that may contribute to positive and negative effects.

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APPENDIX 1 Case Report form

CareLoop: Metacognitive Study

A technology-facilitated self-management system for patients with psychosis

12 week

Assessment

CRF

Contents:

3. SUMD-A (Clinician/Researcher Report, 9 questions)……..…9

Participant Randomisation Code								
Date of Birth	D	D	M	M	Y	Y	Y	Y

Participant Randomisation Code								
Date of Assessment	D	D	M	M	Y	Y	Y	Y
Assessment number (1, 2)								
Name of Assessor								
Signature of Assessor								

1. Beck's Cognitive Insight Scale (from Appendix A, Beck et al., 2004)

Below is a list of sentences about how people think and feel. Please read each sentence in the list carefully. Please circle the degree to which you agree with each statement:

(1) At times, I have misunderstood other people's attitudes towards me.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(2) My interpretations of my experiences are definitely right.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(3) Other people can understand the cause of my unusual experiences better than I can.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(4) I have jumped to conclusions too fast.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(5) Some of my experiences that have seemed very real may have been due to my imagination.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(6) Some of the ideas I was certain were true turned out to be false.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(7) If something feels right, it means that it is right.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(8) Even though I feel strongly that I am right, I could be wrong.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

Participant Randomisation Code						
Assessment number (1,2)						

(9) I know better than anyone else what my problems are.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(10) When people disagree with me, they are generally wrong.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(11) I cannot trust other people's opinion about my experiences.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(12) If somebody points out that my beliefs are wrong, I am willing to consider it.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(13) I can trust my own judgment at all times.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(14) There is often more than one possible explanation for why people act the way they do.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

(15) My unusual experiences may be due to my being extremely upset or stressed.

I----------I----------I----------I

Do not agree at all Agree slightly Agree a lot Agree completely

Participant Randomisation Code								
Date of Assessment	D	D	M	M	Y	Y	Y	Y
Assessment number (1, 2)								
Name of Assessor								
Signature of Assessor								

2. CHOICE

The questionnaire is made up of 20 statements. You can either fill it in on your own, or we can go through it together. It should take 8- 10 minutes to complete.

For each statement, please begin by reading it carefully. You will then be asked to answer the same 2 questions about each statement. Please put a cross on the line for each question to show how you have felt about it **over the last week**. For each statement the questions will be:

(a) How would you rate

yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

Participant Randomisation Code						
Assessment number (1,2)						

1. The ability to approach problems in a variety of ways

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst *best*

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

2. Self-confidence

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

3. Positive ways of relating to people

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

4. The effect of unpleasant experiences (e.g. beliefs, thoughts, voices, feelings) on my life

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

5. Feeling overwhelmed by negative feelings (e.g. fear, depression, anger)

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

6. Knowing I am not the only person who has unusual experiences

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

7. The ability to question the way I look at things

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

8. The ability to relax

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

9. Coping:

(i) Ways of dealing with everyday life stresses

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

(ii) Ways of dealing with distressing experiences (e.g. beliefs, thoughts, voices)

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

(iii) Ways of dealing with unpleasant feelings and emotions (e.g. depression, worry, anger)

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

(iv) Ways of dealing with a crisis

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

(v) Ways of dealing with group situations

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

10. Feeling that there is someone who understands and listens to me

(a) How would you rate yourself for this? 0 1 2 3 4 5 6 7 8 9 10

worst best

(b) How satisfied are you with this? 0 1 2 3 4 5 6 7 8 9 10

not at all satisfied very satisfied

Participant Randomisation Code						
Assessment number (1,2)						

11. The ability to see things from another point of view

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

12. Feeling safe and secure

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

13. Facing my own upsetting thoughts and feelings

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

14. Peace of Mind

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

15. Feeling happy

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

16. Understanding myself and my past

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

17. Understanding my experiences (e.g. beliefs, thoughts, voices, and related feelings)

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

18. Positive ways of thinking

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

19. A positive purpose and direction in life

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

20. A sense of being in control of my life

(a) How would you rate yourself for this?	0	1	2	3	4	5	6	7	8	9	10
	worst										best
(b) How satisfied are you with this?	0	1	2	3	4	5	6	7	8	9	10
	not at all satisfied										very satisfied

Participant Randomisation Code								
Date of Assessment	D	D	M	M	Y	Y	Y	Y
Assessment number (1, 2)								
Name of Assessor								
Signature of Assessor								

3. CLINICIAN OR RESEARCHER RATED: The abbreviated version of the Scale to Assess Unawareness in Mental Disorder in schizophrenia

Items (current awareness)	**Modalities of response**
1. Awareness of mental disorder: In the most general terms, does the subject believe that he or she has a mental disorder?	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3
2. Awareness of the consequences of mental disorder: What is the subject's belief regarding the reason(s) he or she has been unemployed, evicted, hospitalized, etc.?	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3
3. Awareness of the effects of drugs: Does the subject believe that medications have diminished the severity of his or her symptoms?	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2

	Seriously unaware = 3
4. Awareness of hallucinatory experiences: Does the subject believe that he or she experiences hallucinations as such? Rate his or her ability to interpret this experience as primarily hallucinatory.	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware =2 Seriously unaware = 3
5. Awareness of delusional ideas: Does the subject believe that he or she experiences delusions as such, that is, as internally produced erroneous beliefs ? Rate his or her awareness of the implausibility of the belief if applicable.	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3
6. Awareness of disorganized thoughts: Does the subject believe that his or her communications are disorganized?	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3

Participant Randomisation Code						
Assessment number (1,2)						

Items (current awareness) **Modalities of response**

7. Awareness of blunted affect: >Rate the subject's awareness of his or her affect as communicated by his or her expressions, voice, gestures, etc. Do not rate his or her evaluation of his or her mood.	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3
8. Awareness of anhedonia: Is the subject aware that his or her behaviour reflects an apparent decrease in experiencing pleasure while participating in activities normally associated with such feelings?	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3
9. Awareness of lack of sociality: Is the subject aware that he or she shows no interest in social relationships?	Not applicable = 0 or missing Aware = 1 Slightly aware/ unaware = 2 Seriously unaware = 3

APPENDIX 2

Participant Information Sheet

The effect of self-monitoring using novel mobile experience sampling method (ESM) technology on metacognition in psychosis

We would like to invite you to take part in a research study. Before you decide whether or not to take part, please read this information sheet. It explains what the research is about, why it is being done and how you could be involved. If you would like to take part or you have any questions about the study please contact the research team in your area using the contact details on the back page. You might wish to speak to someone who you trust to ask their opinion too.

What is the study about?

Previous research has shown that some people with severe mental health problems may not always be aware that they are experiencing symptoms. At times this can be a significant barrier to accessing helpful treatment and support. This study will discover whether monitoring your symptoms and mood every day has an effect on understanding your mental health and diagnosis. Active monitoring might help people gain more of an understanding of how their mood, behaviour and symptoms interact. It may also help people become aware of certain triggers and situations that make their symptoms better or worse.

The purpose of the current study is to investigate some of the effects of active self-monitoring using the mobile phone ClinTouch. We will invite participants in the ClinTouch study from both the ClinTouch (mobile phone use) and comparison (no mobile phone use) groups. We will ask you to complete a few more measures to help us assess whether your understanding changes after you have taken part in the ClinTouch study. Those in the mobile phone use group will also be invited to attend a short interview about their experience.

The results of this study will improve our understanding of the potential effects of using the ClinTouch mobile phone app on people's understanding of the links between feelings, behaviours and symptoms. We hope that this mobile phone app will also help individuals gain a better understanding of what may help them on their recovery journey.

Who is doing the research?

This project is being carried out by the University of Manchester and the Institute of Psychiatry, King's College London in collaboration with Manchester Mental Health and Social Care Trust and South London and Maudsley NHS Foundation Trust.

Why have I been invited?

You have been invited to participate in the study because you have experienced psychosis and are taking part in the ClinTouch study; participants of the ClinTouch group (mobile phone use) and comparison group (no mobile phone use) are invited to take part.

Do I have to take part?
Your participation is entirely voluntary and you do not have to take part. You are free to withdraw at any point without giving a reason. If you agree to participate, you will be asked to sign a consent form.

What will happen to me if I take part?
Consent and First Assessment session
If you decide to take part in the study, we will ask you to meet with us. We will go through this information sheet with you and answer any questions you may have. We will then ask you to sign a consent form to show you have agreed to take part. After this we will ask you to complete a few questionnaires which will take about 20 minutes.

Final assessment session
If you are part of the ClinTouch group after 12 weeks of using the ClinTouch mobile phone you will be invited to take part in the final assessment. If you are part of the comparison group who did not use the ClinTouch mobile you will be invited to take part in the final assessment after 12 weeks of receiving care from your doctor, nurse or mental health worker as usual.

At the final assessment session you will be asked to complete the same questionnaires as in the first assessment which should take approximately 20 minutes. This session enables us to measure if psychological processes change over the course of using the ClinTouch mobile phone.

Extra Interview
If you are part of the ClinTouch group, during the final assessment you may be invited to attend a brief interview. During this interview we would like to better understand your experience of tracking your symptoms using the mobile. The length of the interview is flexible but is likely to be around 20 minutes long. The interview will be informal and you will be asked a range of questions. The interview will be audio-recorded but your real name will not be used in any subsequent written report or published material. The recordings and written notes based on these interviews will be securely stored at King's College London. The interview recordings will be destroyed once they have been typed up.

Will I still receive normal care?
You will receive normal care whilst participating in this study and whilst using ClinTouch.

Will I be paid?
We will pay travel expenses to and from the research site e.g. if you attend an interview outside of your own home. The payment schedule for each session of the ClinTouch study is outlined in the 'Participant information sheet: ClinTouch-CareLoop version 3.1'. Participation in this study will mean additional shopping vouchers of £5 for your first 20 min session and £10 for your second 20 min session for a total of £15. If you agree to do the extra interview you will be paid an additional £5 in vouchers.

Involvement of the general practitioner (GP) and psychiatrist
With your consent we will tell your GP and psychiatrist that you have agreed to take part in this study. What you say during interviews will remain confidential and will not be discussed

with healthcare staff unless you ask us to do so. The only exception to this will be if the researcher becomes concerned that you may be at serious risk of harming yourself or others. If this is the case, the researcher will raise these concerns with your health care provider.

What if there is a problem?
In the event of any question or complaint about how this study has been run, in the first instance please contact one of the researchers whose contact details can be found below. If they are unable to resolve your concern or you wish to make a complaint regarding the study, You can also contact the Patient advice and Liaison Services (PALS) in your area:

Manchester PALS

PALS, MMHSCT
11th Floor, Hexagon Tower
Crumpsall Vale
Manchester. M9 8GQ
Tel: 0161 882 2084 Ext. 2085
Email: PALS@mhsc.nhs.uk

London PALS

PALS, The Maudsley Hospital
Denmark Hill
London
SE5 8AZ
Tel: 0800 731 2864
Email: pals@slam.nhs.uk

Researcher Contact information:

Dr Clare Killikelly and Professor Til Wykes

Institute of Psychiatry, Psychology and Neuroscience

PO BOX 78

De Crespigny Park, London

SE5 8AF

Email: clare.killikelly@kcl.ac.uk

MANCHESTER 1824

The University of Manchester

Institute of Psychiatry

KING'S College LONDON

Henry Wellcome Building

King's College London

SE5 8AF

Tel: 020 7848 5411

CONSENT FORM

Study Title: The effect of self-monitoring using novel mobile experience sampling method (ESM) technology on metacognition in psychosis Version 2.0

Name of principal researcher: Prof Til Wykes

Please initial the box if you agree with the statement

1.	I confirm that I have read and understand the information sheet (dated ____v___) for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my care being affected in any way.	☐
3.	I agree to my healthcare team and GP being informed about my participation in the study.	☐
4.	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Manchester, The Institute of Psychiatry at King's College London, from regulatory authorities or from the applicable NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data	☐
5.	I understand that when this research is completed the data and audio file will be retained and securely archived for a period of 10 years. This archive can only be accessed by request from the research team and all files will be destroyed at the end of that period	
6.	I give my consent for GCP trained researchers to have access to my medical notes, where it is relevant to me taking part. I understand that they follow a code of ethical conduct and are bound by a duty of confidentiality.	☐
7.	I agree to be contacted about other ethically approved studies	Yes ☐ No ☐
8.	I agree to the use of anonymised quotations from interviews being reported in research reports, journal articles and presentations.	☐

9. I agree to take part in the qualitative interview study Yes ☐ No ☐

10. I understand that the qualitative interview will be recorded and transcribed ☐

_____ _____ _____

Name of Participant Date Signature

_____ _____ _____

Researcher Date Signature

Please complete both copies of the consent form and keep one for your own record

APPENDIX 3 ClinTouch Info

Thank you for taking part in the ClinTouch study.

Here are some basic instructions to help you get started. If you want to see more information about how to use ClinTouch please tap 'instructions' once the app is open or touch the 'help' button whilst you are using the app.

If you experience any problems with the app or would like more information or support please contact us:

Manchester Office

Contact: Sally Preston
Tel: 0161 275 3959

sally.preston@manchester.ac.uk

London Office

Contact: Zhimin He,
Tel: 020 7848 5411

zhimin.he@kcl.ac.uk

Our offices are open between 9am and 5pm from Monday to Friday.

ClinTouch is designed to help you keep track of symptoms from day to day and to discuss this information with your key worker at routine meetings. It cannot help you seek support if you are in an emergency situation.

If at any point during the study you feel in crisis or suicidal please seek help from a friend, family member, GP, keyworker, telephone helpline or from your local hospital emergency department.

Useful helpline telephone numbers

Samaritans
Tel: 08457 90 90 90

Mind information line
Tel: 0300 123 3393

SANEline
Tel: 0845 767 8000

NHS Direct
Tel: 0845 46 47

Manchester Crisis Point
Tel: 0161 839 5030

South London and Maudsley Crisis Information Line
Tel: 0800 731 286

ClinTouch Instructions

1. When should I use the ClinTouch app?

- You only need to use ClinTouch when you hear a set of short 'beeps' coming from the phone. We call these 'beeps' an alert. An alert will sound four times a day for the 12 weeks that you are taking part in the study.
- When you hear the alert, this means it is time to answer the questions.
- If you tap, 'answer questions,' the first question will appear.
- You do not need to use ClinTouch at any other time unless you want to use it.

2. How many alerts will I receive?

- You will receive four alerts per day, every day for twelve weeks.
- The alerts will start being delivered to your phone the **day after** your key worker meets with you to agree the settings.

3. How many questions will I need to answer each time an alert arrives?

- The number of questions you answer will depend on the answers that you give but you will never be asked to answer more than 18 questions during an alert.
- It is important that you do not spend too long thinking about the answers you give.

Your first instinct is usually the right answer!

- Most people who use the ClinTouch app complete all the questions in less than 2 minutes.

4. How do I answer and move between questions?

- When you have heard the alert and tapped the 'answer questions' button some writing will appear with a coloured bar beneath it.
- Tap the bar in the centre and slide the ball up or down to say how much you agree or disagree with the words above it.
- For example, you might see the words, 'I feel optimistic about the future'. If you are feeling positive about the future at that moment you should slide the ball towards the word 'agree'. If you are not feeling optimistic about the future at that moment you should slide the ball towards 'disagree'.

- Once you have decided how much you agree or disagree with the words by moving the ball up or down you should tap ‘next’ to move to the next question.
- You can slide the ball up and down the bar as many times as you like until you are happy with your answer, but we ask that you answer the questions as quickly as you can without thinking about them for too long.
- You will not always see every question at every alert and the questions will not always come in the same order. This is because what you see will depend on how you have answered the previous questions.
- Once you have completed the questions a box will pop up telling you that the questions are complete and the ClinTouch application will close.
- If you have chosen to see a positive thought or picture, ClinTouch will show you this before closing the questions and taking you back to the main screen.
- You can then re-place the phone in a safe place until you hear the next alert.

5. What if I am finding it difficult to answer a question?

- Please try to answer all of the questions. If you experience any difficult feelings when answering a question and would like to speak to someone from the study team please call us using the contact details provided.

6. What if I am busy when I hear the alert?

- You will be given the chance to delay the questions just once for five minutes.
- You can do this by tapping the ‘snooze’ button, instead of the ‘answer questions’ button, when you first hear the alert.
- The phone will then beep again after five minutes have passed.
- If you miss the second beep you will not be able to complete the questions again until you hear the next beep.

7. What happens if I miss an alert?

- Don’t worry; just listen out for the next beep.
- If you missed the alert because you could not hear the phone, please move it to somewhere you can hear it better or try pressing the top part of the grey volume button. This button can be found on the left-hand side of the handset. It is best to press this button when the next alert arrives. This should increase the volume. If you still cannot hear the alerts please contact us using the details we have provided.

8. Where should I keep the phone?

- Please try to keep your phone with you between 9am and 9pm every day during the twelve weeks you are taking part in the study. It is usually fine

to leave the phone out somewhere you can hear it at home. If you go out please make sure you take your phone with you in a zipped pocket or bag and make sure that you can still hear it.

9. How often should I charge the phone?

- Please charge the phone overnight at least three times a week, or when the green battery sign is running low, using the charger we have provided. Thanks. The more you use the phone the more charge it will need.

10. Can I make or receive calls from / to the phone?

- You cannot make or receive phone calls as there is not enough credit to do this.

11. Can I change the appearance or settings on the phone, e.g. screen saver, volume or ringtones?

- Please do not change any of the phone settings or download any new apps. The appearance and sound of the phone have been set to appear in a certain way and ring at the right volume. Thanks for your cooperation.

12. Can I adjust the volume that the phone beeps?

- Your keyworker will adjust the volume of the alert to your liking during the first appointment. Please do not change the volume settings or switch the sounds off.

13. How do I wake the phone up when it is in the 'locked' mode?

- Briefly press and release the grey button on the right hand side of the phone near the top.
- Once the page is lit up, slide your finger across the screen in a horizontal direction.
- If the phone is unlocked you will see the main screen showing the time and date.

14. How do I switch the phone on and off?

- The phone can stay switched on for the duration of the study provided that you charge it regularly.
- If you would prefer to switch the phone off overnight, please press and hold down the grey button on the right hand side of the handset and tap the option to 'power off'.

- Press and hold down the same button to switch the phone back on again. You will need to press this button down for at least 3 seconds before the phone will switch back on again.
- The alerts should not disturb you at night because ClinTouch does not beep between 9pm and 9am. If you hear any alerts after 9pm please check what time it says on the main phone screen and contact the research team.

15. How often will I see or speak to the research team?

- We will ring you once a week just to check whether you would like any support on the contact number you would prefer, but please feel free to call us if you need any help before then. Thank you for your help

APPENDIX 4 ClinTouch Mobile phone questions

Question set 1:
Hopelessness
I have felt optimistic about the future (reversed)
I have felt that there is little point in trying
I feel like the future holds little for me
I feel like giving up

Depression
I have felt sad
I have felt miserable
I have had no interest in seeing other people
My mood has affected my appetite or sleep
I have felt worthless
I have had thoughts about harming myself

Hallucinations
I have heard voices
I have found it difficult to concentrate on other things
This stopped me from doing things
Hearing the voice(s) upset me
I have seen things that other people can't see
I have found it difficult to concentrate on other things
This stopped me from doing things
Seeing these things upset me

Question set 2:
Anxiety
I have felt worried, nervous or anxious
My heart has been racing or I have been shaking
My anxiety has stopped me from doing things
This has affected my appetite or sleep

Grandiosity
Compared to the average person, I am
I have felt like I am special
I have felt like I have powers or abilities that other people don’t have

Suspiciousness
I have worried about saying too much
I have been suspicious
I have felt like someone or something meant me harm
This has stopped me from spending time with others
This has stopped me from doing things

I have found it difficult to concentrate on other things

Delusions (if any) follow after this - up to 4 questions for each delusion

Each user may have two delusion questions added to the battery, and each delusion has three follow-up probe questions (‘this upset me’, ‘this stopped me from doing things’ and ‘I have found it difficult to concentrate on other things’). The 12 delusions are:

1. I have felt like I could read other people\'s thoughts
2. I have felt like other people were reading my thoughts
3. I have felt that my thoughts were being controlled or influenced

4. I have felt like my thoughts were alien to me in some way
5. I have felt like the world is not real
6. I have felt like I am not real
7. I have felt like people were not what they seemed
8. I have felt like things on the TV, in books or magazines had a special meaning for me
9. I have felt like there was a conspiracy against me
10. I have been jealous
11. I have felt like something bad was about to happen
12. I have felt distinctly concerned about my physical health

APPENDIX 5 Qualitative Questions

Metacognitive CareLoop Study Qualitative Questions: 12 week Outcome interview

Ensure consent for audio recording: YES☐ NO☐

Topic Guide covers 5 main topics. The *sub-questions* **below the main topic questions can be used as a guide but should be open questions when possible**

TOPIC 1: CLINICAL INSIGHT: awareness of medical problem

1. Do you believe you have a mental health problem?

- *What is your main problem or difficulty at the moment?*

2. Did you learn anything from monitoring your mood and symptoms over the past 3 months that suggests that you have a mental health problem or difficulties?

- *How does this make you feel?*
- *(if no) Does anything suggest that you do **not** have a mental health problem?*

TOPIC 2: COGNITIVE INSIGHT: awareness of thoughts and cognitions

3. After monitoring your mood, symptoms and behaviour do you have any alternative understanding of your unusual experiences (or negative symptoms, or social withdrawal or paranoia (when applicable))

- Does this cause you any worry or distress?

4. After self-monitoring with the app are you aware of any errors in your thinking or interpretation of experiences?

- Does this cause you any worry or distress?

TOPIC 3: METACOGNITIVE REGULATION; awareness of the effect of self monitoring

5. Is it important/helpful to self monitor? For example, to keep track of specific patterns or connections between mood, behaviour and symptoms? Why or why not? will you continue to self monitor without the app?

6. Can you tell me about any *specific* patterns in your mood or symptoms you noticed while using the app?

- *Any connections between how you feel and your symptoms?*
- *Any connections between what you were doing and your symptoms or mood?*
- *Did you notice anything about your environment that affected your mood, symptoms or unusual experiences? (eg time of day, specific events, places or people?)*

7. Are these new patterns that you had not noticed before? (eg new triggers, effect of new medication, drug/alcohol use) was there anything unexpected in your ratings?

- *(if no) Did using the app confirm what you already knew about yourself and symptoms?*

TOPIC 4: Metacognitive Knowledge; awareness of own beliefs

8. Do you believe that you are more self-aware (eg aware of your thoughts and feelings) since monitoring your mood, symptoms and behaviour with the app? Can you give me an example? Do you have a better understanding of yourself?

9. After self monitoring with the app do you believe that you are managing and able to cope with your difficulties? Do you do anything differently now since using the app?

10. Empowerment and control: since using the app have you felt more in control of your mental health? Have you learned anything positive about yourself?

TOPIC 5: SUPPORT

- Tell me about the support you received from your care coordinator during the 12 weeks ClinTouch study:
    - *Did you and your care coordinator use the data from the mobile app to discuss your symptoms, mood or warning signs? Would this have been helpful? Would you have liked more support from your care-coordinator during these 12 weeks?*
    - *Did keeping track of your symptoms alert you to times when you might be going into crisis and need extra support?*

APPENDIX 6 Method of Qualitative Analysis

1) Data Coding

Below is a sample of how the interview data was summarized and organized into deductive codes. The data was entered in excel to form a framework matrix (see Figure 1 for an example of how the data is organized); the interview topic questions (or deductive codes) are entered in the columns and the rows represent the individual cases. The data was first coded using the deductive codes according to each of the structured interview questions e.g. *1.1 Do you believe you have a mental health problem.*

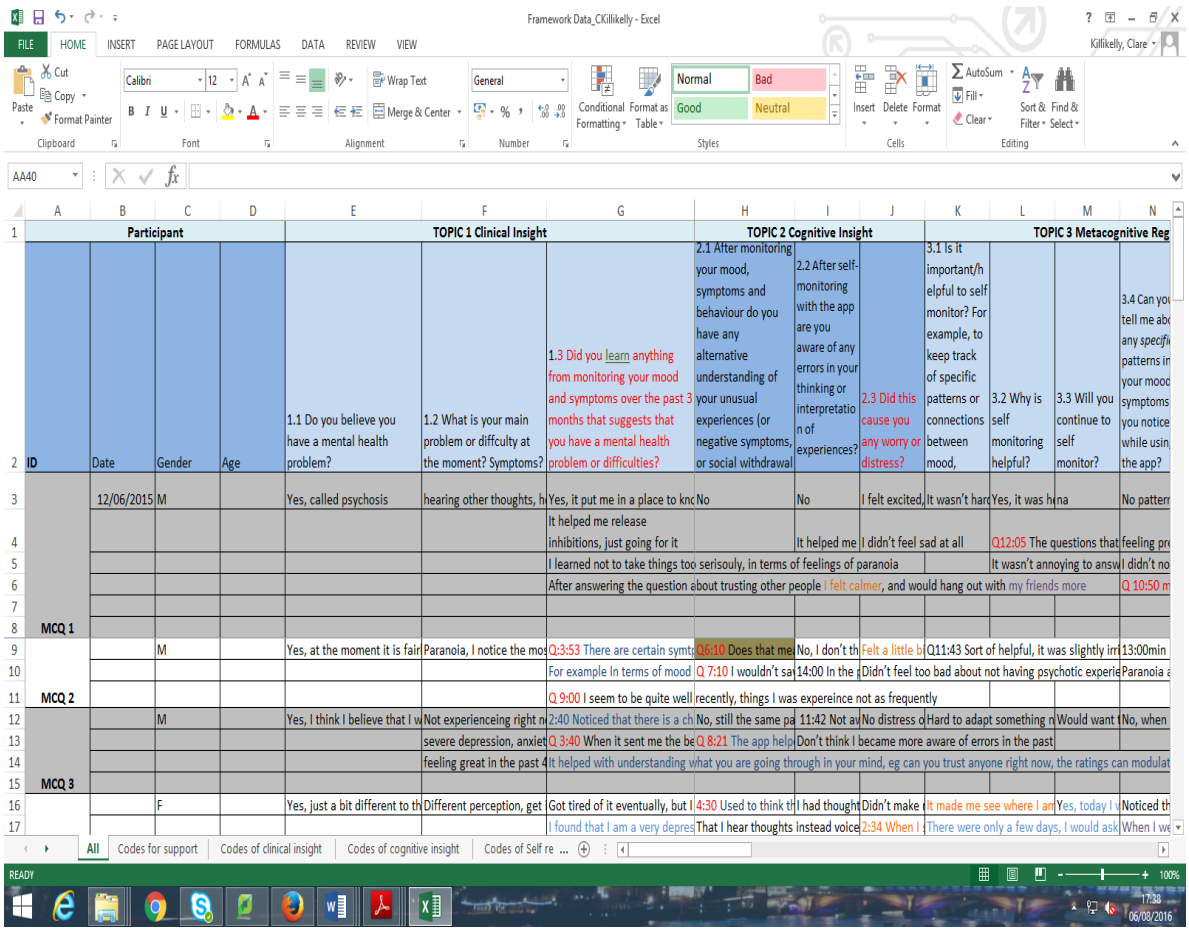

Figure 1 Sample from the Microsoft excel to show the organization of the Framework Matrix for deductive and inductive coding

Next the data were coded across the whole data set according to inductive codes such as recovery, noticing patterns, understanding of self or experiences. These codes are represented with different colours. Exemplar quotations were noted with a red 'Q'.

Please see Neale (2016) Figures 1-7 for more examples of a sample of iterative categorization.

2) Data Analysis: Iterative Categorization

After the data were coded using the framework matrix, each interview topic question was analyzed in a separate word document. The data for each participant was analyzed line by line and categorized under different themes and subthemes that emerged from the data. For example Figure 2 displays how the responses to the question 'Do you believe you have a mental health problem' were categorized into two main themes; theme 1 *identification of psychosis or schizophrenia*, theme 2 *Description of symptoms*.

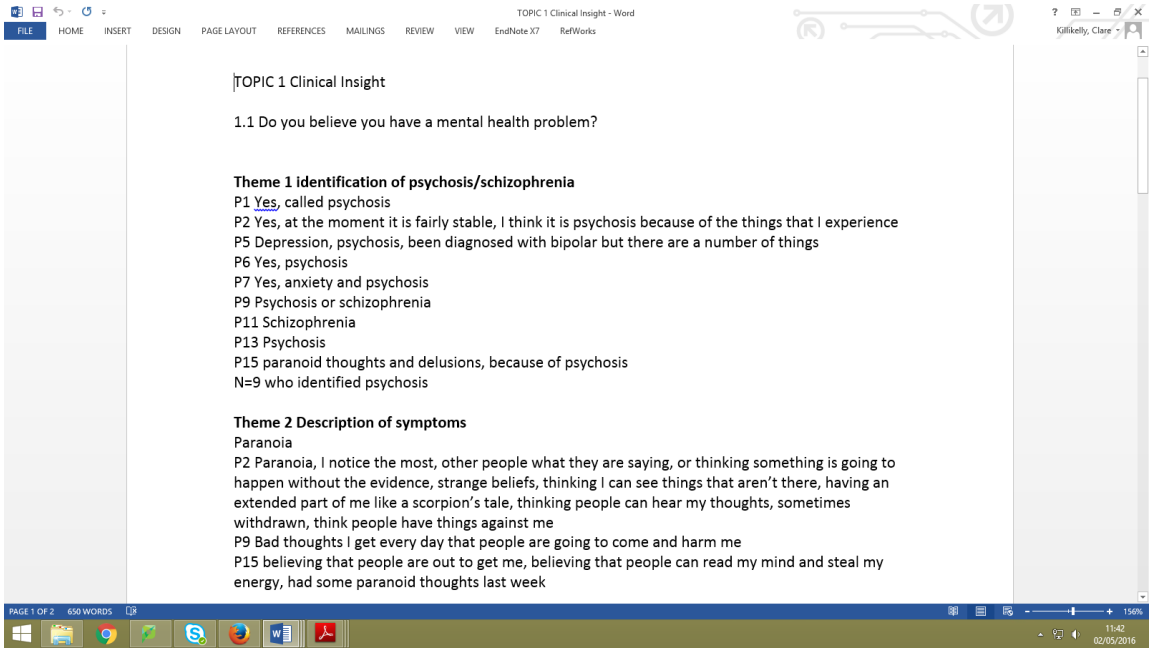

Figure 2 Iterative Categorization of participants responses to question 1.1 Do you believe you have a mental health problem?

APPENDIX 7 Quantitative Results and Figures

Figures depicting nonsignificant results are presented below.

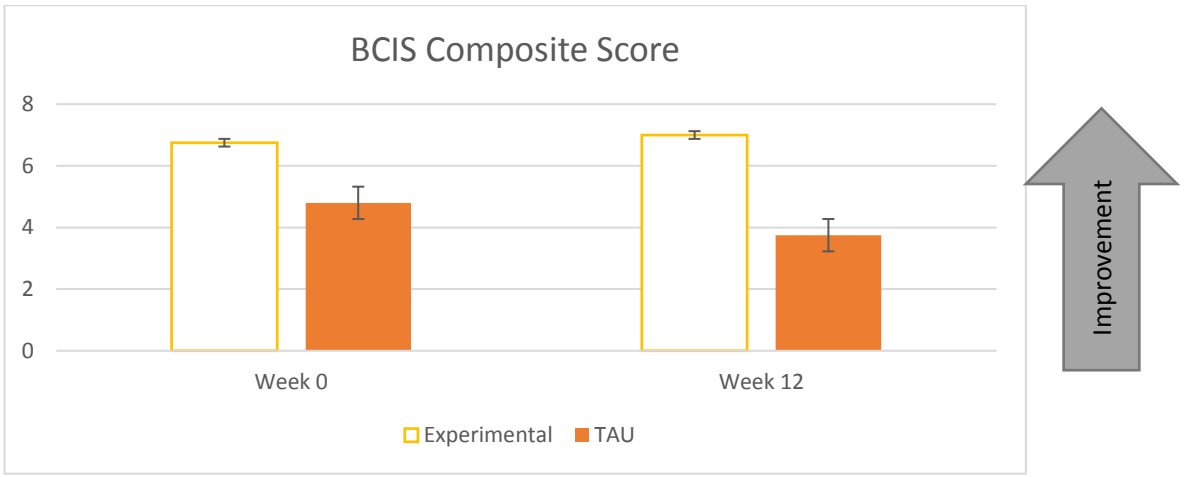

Figure 1 Means and standard errors for baseline and week 12 scores for the BCIS Composite scale

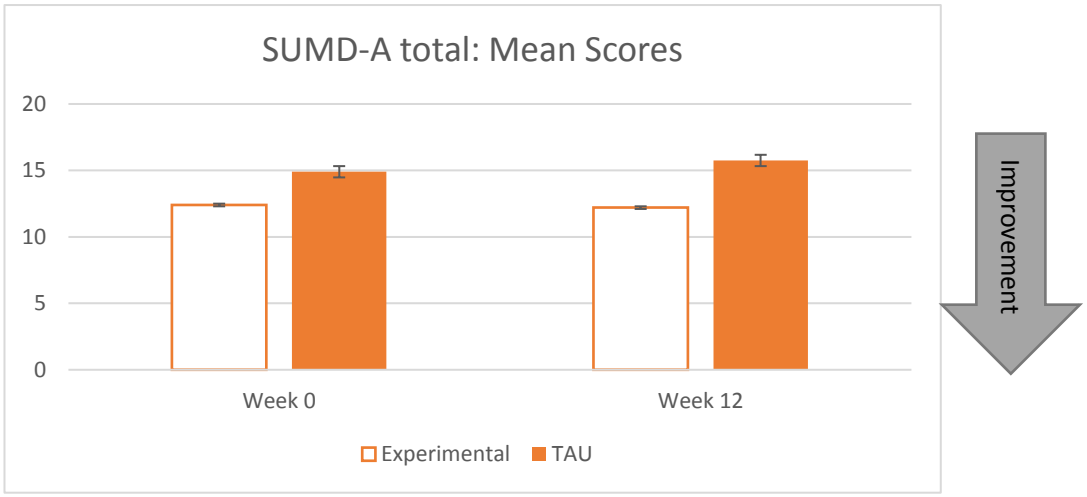

Figure 2 Means and standard errors for baseline and week 12 scores on the SUMD-A total variable

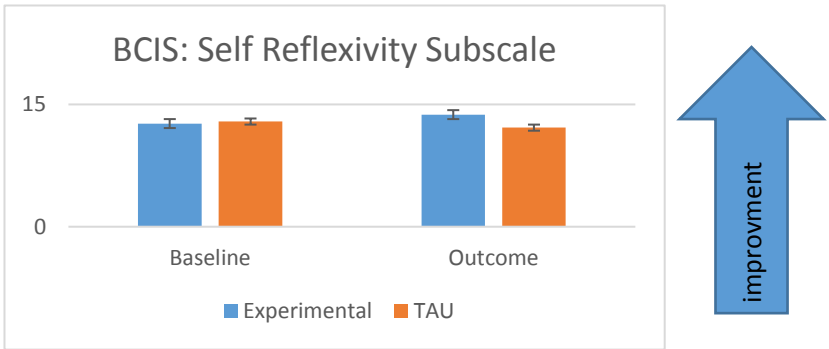

Figure 3 Mean baseline and outcome scores on the BCIS self-reflexivity scale

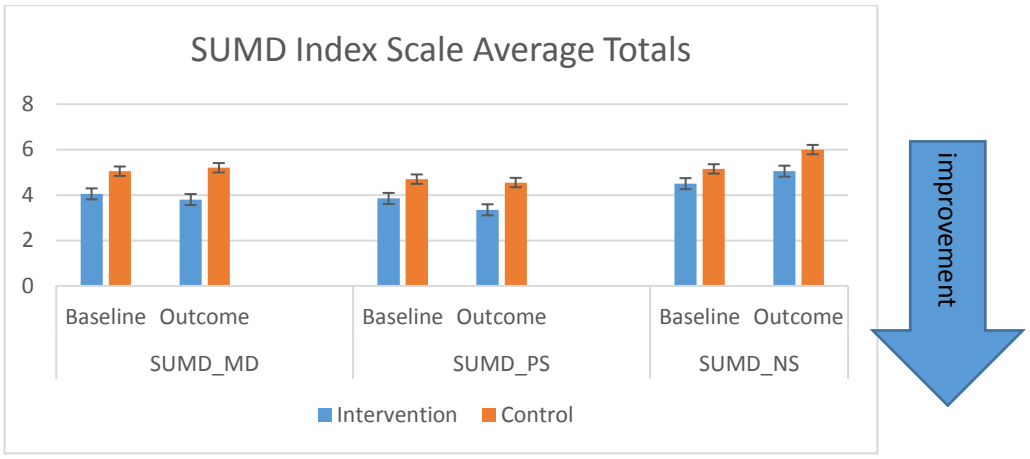

Figure 4 SUMD-A index subscales for Mental Disorder (MD), Positive Symptoms (PS) and Negative Symptoms (NS)

Figure 5 Mean scores on the CHOICE subscales of severity and satisfaction

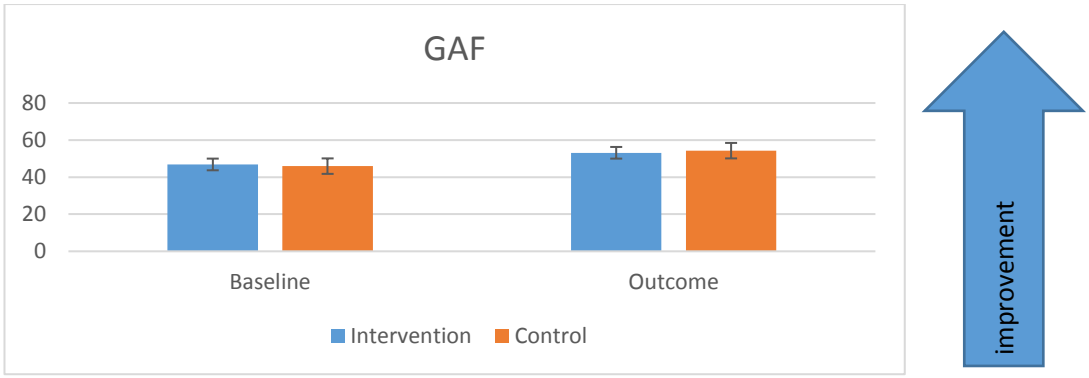

Figure 6 Mean scores at baseline and outcome for the Global Assessment of Functioning scale

TABLE 5 PARTIAL CORRELATIONS CONTROLLING FOR BASELINE SCORES BETWEEN CHANGE IN INSIGHT MEASURES AND TOTAL ENTRIES COMPLETED. [1]INDICATES POTENTIAL TREND.

Measure	Partial correlation on change score
BCIS: Self reflexivity	r=.172, p=.482
BCIS: Self certainty	r=-.037, p=.882
BCIS: Composite score	r=.231, p=.342
SUMD-A: sum total	r=.405, p=.085[1]
SUMD-A: MD	r=.098, p=.691
SUMD-A: PS	r=.099, p=.687
SUMD-A:NS	r=.428, p=.067[1]
CHOICE: Severity	r=.-.317, p=.186[1]
CHOICE Satisfaction	r=.-.347, p=.115[1]

TABLE 6 PARTIAL CORRELATIONS BETWEEN CHANGE IN SYMPTOMS/FUNCTIONING AND TOTAL ENTRIES COMPLETED, [1]INDICATES NOTABLE TRENDS

Measure	Partial Correlation on change score
PANSS: Total	r=.243, p=.317
PANSS: Positive Scale	r=.369, p=.120[1]
PANSS: Negative Scale	r=.377, p=.112[1]
PANSS: General Scale	r=.056, p=.818
GAF	r=-.343, p=.151

TABLE 7 NOTABLE PARTIAL CORRELATIONS FOR ADDITIONAL MEASURES OF ADHERENCE: * STATISTICALLY SIGNIFICANT

Additional Adherence Measures	Partial Correlations on change scores
Week 1	
SUMD-A NS	r= .420, p=.073
PANSS Total	r=.417, p=.076
PANSS PS	r= .452, p=.053
PANSS NS	r=.674, p=.002*
Week 12	
SUMD-A total	r=.600, p=.007*
SUMD-A NS	r=.439, p=.060
# of days adherent	
SUMD-A NS	r=.425, p=.069
GAF	r=-.405, p=.085

APPENDIX 8 Qualitative Results

Iterative Categorization of three interview topic questions

The process of iterative categorization for the three interview topic questions is presented below. The main themes identified are presented in bold and the emergent subthemes are underlined.

TOPIC 1 Clinical Insight

1.1 Do you believe you have a mental health problem?

Theme 1 identification of psychosis/schizophrenia
P1 Yes, called psychosis
P2 Yes, at the moment it is fairly stable, I think it is psychosis because of the things that I experience
P5 Depression, psychosis, been diagnosed with bipolar but there are a number of things
P6 Yes, psychosis
P7 Yes, anxiety and psychosis
P9 Psychosis or schizophrenia
P11 Schizophrenia
P13 Psychosis
P15 paranoid thoughts and delusions, because of psychosis
N=9 who identified psychosis

Theme 2 Description of symptoms
<u>Paranoia</u>
P2 Paranoia, I notice the most, other people what they are saying, or thinking something is going to happen without the evidence, strange beliefs, thinking I can see things that aren't there, having an extended part of me like a scorpion's tale, thinking people can hear my thoughts, sometimes withdrawn, think people have things against me
P9 Bad thoughts I get every day that people are going to come and harm me
P15 believing that people are out to get me, believing that people can read my mind and steal my energy, had some paranoid thoughts last week

<u>Hearing voices/thoughts</u>
P1 hearing other thoughts, hearing other people's thoughts, how I interact with people is a bit strange
P11 Main difficulty at the moment is hearing voices, I've got used to it but it is still on going

<u>Combination of experiences</u>
P7 panic attacks, mood alterations, depression, hear voices, still experiencing all of them
P5 When I have a lot of stress I end up making things up as I go along, overwhelming feelings that I want to be special, borderline mania
P6 damage to the brain, get these weird feelings to the brain sometimes, I'll be itching my brain, it is from when I was smoking weed, like a headache running from the back of my head
P11 In the past Paranoia, anxiety, hallucinations, feelings that people could read my thoughts and people were trying to harm me
P13 Hearing voices and paranoia

P3 Not experiencing right now, because everything has been so positive, no problems or effects,

Theme 3 Yes, but not necessarily psychosis

Experiences in life

P3 Yes, I think I believe that I was going through a period of a mental health episode, but not a mental health problem, things just came on top, I don't suffer from a mental health difficulty, just trauma from my life just all came on top of me

P6 main problem at the moment is not being allowed to smoke weed

P8 Main problem is back pain

P8 Mostly been in the past, wrong use of alcohol, being misunderstood in the past, trying to talk to people and trying tell them what I was going through my mind, someone was telling me the wrong thing, in the long run, things from the past started building up

Different ways of thinking

P8 thinking is not quite right, not the same as other people

P4 Yes, just a bit different to the normal person, Different perception, get ideas in my head but someone else will deem them not true, I still believe that some of the things I went through are true, just going with medication because they say it's good

P8 Mental and physical distraction, bad pattern that set in that is not normal

P10 Confidence, believing in myself

P10 I think so, my way of thinking, sometimes I just shut down, I get anxious, confusion

Theme 4 No identification of psychosis

P12 I don't really know 100%, I am addicted to medication so I need to keep taking it

P12 The council and social services haven't done their job to look after me, there was a time that I was desperate for help and ended up in hospital, had to take medication and now I am in horrible situation

P14 I don't really feel like I have a difficulty

TOPIC 2 Cognitive Insight

2.1 After monitoring your mood, symptoms and behaviour do you have any alternative understanding of your unusual experiences (or negative symptoms, or social withdrawal or paranoia (when applicable)

Theme 1 Developed New understanding of self/experiences

Understanding that it was in mind/not reality

P4 That I hear thoughts instead voices, still waiting for the one year mark to make sure that it is just thoughts and the voices havent come back

P4 When it mentioned voices I would click about a 2 meaning not at all but when it was thoughts I would click higher, so I would start to distinguish it in a way

P4Now I know it is my thoughts

P8 I just realized that it was my imagination sometimes I would see like a ghost

P7 Using the phone let me know that they were not really there

Understanding of symptoms as mental illness:

P3 The app helped to understand that paranoia was a symptom and it is something you are going through and not reality, knew that I was going through something so I would try and understand it more, you can talk to yourself about it and understand it

P6 Previously I was getting into problems with people and thinking that they were going to harm me, this was the symptoms of psychosis, I understand this better now, as I got the phone I understood that I wasn't answering the psychosis questions

Understanding of experiences

P13 but the question about hearing voices and trusting other people, I noticied I did trust other people, I hadnt really given it too much thought before, after doing the study did feel like could trust people more
P1 It helped me to understand that these experiences in the past weren't real in the past,
P13 How do you see yourself compared to the average person, felt normal

Theme 2 Emerging understanding

Noticing Connections
P12 Difficult to say, but gives me an idea that what the medication helps me with, ask why are these questions here
P12 Sometimes, it was unusual experience every time there was a new feeling and emotions, try to understand it and figure it out
P14 I may have been a bit happier when I was around certain people, but I was always thinking positively so that helped, didn't really matter what I was doing
P10 Monitor my thinking and feeling as the day goes on, and to help me see what are the things that are helping my thinking
P11 At the moment I think that if I get too stressed then I start to get more symptoms of my mental health condition

Questioning Experiences
P15 When I was paranoid at work I just believed them to be true, but I wasn't 100% sure, after speaking to care coordinator she explained that I don't have any evidence to back up these thoughts, so then I decided that they probably werent true
P2 Does that mean that I don't have psychosis, if I don't experience one of the main symptoms? Or maybe it is a good sign that this is recovery
P4 Used to think that people choose what they wear and the colours has a special meaning and reading into their thoughts feelings, used to be very focused on this, overtime using the mobile phone doing the questionniare and talking to Michelle, let that go, concentrating on myself more and what makes me happy instead of focuses on others
P10 changed my thinking, trying to see life from a different perspective

Notice symptoms
P5 Helped to realize that hearing voices was happening quite frequently
P9 The fear is still there, even though nothing bad happens
P9 Its just like a constant cycle, don't know when that cycle is going to end, just taking it oneday at a time
P13 confirmed that I have some difficulties
P3 No, still the same paranoia as I had before, but I identified it a bit more, I got to understand certain levels of paranoia, can differentiate how you feel when you use the app, the help clarified how you were feeling

Theme 3 No understanding from using app

Confusion
P7 Not until I met the Dr yesterday, I didn't have an understanding and I don't know why, At first I thought it was just part of the anxiety, but the voices have to do with psychosis as well, it was confusing at first
P2 I wouldn't say so, more confusion about symptoms, questioning if I have psychosis

No patterns
P7 Monitoring didn't help because hearing voices is random, the intensity and when it occurs is random

P8 monitoring didn't really help with this
no new understanding of the voices or visions
P11 I wouldn't say so, I did glance at the charts once, my symptoms did seem to be going up and down but most of the time I wasn't really monitoring the charts
P15 after monitoring I didn't really think about it too much, didn't stop to think about the questions
P6 Don't have a different understanding, now I am fine I don't feel that there is anyone trying to harm me, I am better when I don't smoke

---

TOPIC 3 Self-monitoring, Metacognitive Regulation
3.1 Is it important/helpful to self-monitor? For example, to keep track of specific patterns or connections between mood, behaviour and symptoms?

Theme 1 Time for Reflection
Questioning and asking self
P2 but sort of having a think about the way that I felt was helpful bc it got me questioning why am I thinking that
P6 It helped me to think about things, and also wonder how long am I going to have this phone
P5 Ask myself how I feel once in a while
P12Going through words and visually the words into your mind means that you talk about your problems, it means that there is a way out
P14 A lot of people don't do that, a lot of people are too busy, they ask other people, but don't think to themselves how am I doing, made me consider my own feelings instead of everyone else's, noticed that I was feeling quite good the majority of the time

Changes from day to day
P4 It made me see where I am at which part of the day, there were some days when I was happy
P5 Helped to notice symptoms, didn't know that anything was wrong until recently, app confirmed how things were changing from day to day
P13 Yes, you could see from day to day how things were going and how things were changes
P15 It helped me see that things aren't always good, notice more the changes that I experience more in my thoughts, see that sometimes I am more paranoid and sometimes more optimistic and sometimes I'm not, the app highlights the fluctuations and the different ways that you think

Learning and noticing
P5 Yes, any knowledge about things help you, by paying more attention to it I got more knowledge about
P10 Step back and see life and notice that I was keeping track of my thoughts and mood
P10 Yes, it did help, you just start to notice more
P7 Sometimes it would be helpful, sometimes feel under the weather and it would take my mind off of my mood at the time, I knew that I was helping someone, so I was happy to do it
P11 Understanding how I am feeling, and acknowledging how I am feeling at the time, good or bad and let me think about it more

Theme 2 Realization about self
Understanding symptoms P4 I was more judgemental, before using the app I never thought I was a depressed person
Noticing recovery P6 Phone was helping me to understand that I wasn't having these symptoms anymore, I could still hear people moving around and not so nice people, sharing a bathroom again, was disgusting, but I was still doing ok and wasn't hearing muffled voices or thinking people were at my door, felt safer

P6 Phone was asking me silly questions, I realized that I wasn't going through any of those questions, eg questions like do you think people are trying to harm you, helped to reflect and realized I wasn't going through any of that stuff
P13 Feeling worried nervous and anxious realizing that there were sometimes when I was and sometimes when I wasn't, I wasn't as worried as I thought I would be
P14 Yes, it was, confirmed that I was doing well

Theme 3 Do something about it
Activities P4 There were only a few days, I would ask myself am I really that miserable? I put on a smile on my face but when I go home I am very down, how to you change being down? Trying to do more activities to do, but until I find something with a purpose it is hard to be happy

Questioning what can I do P4 Yes, today I was so moody all the time in the morning, so now trying to find a way to change that
P7 Not necessarily a check in, every few days I look back on the last few days and I think about how things have been for my mood and what I could have done to change my mood, think about how I can change what I can do to avoid having a bad mood, if I feel slightly anxious before I go out then I wont go out, the phone helped to keep track of how anxious I was feeling
P11 It was a new experience, it was slightly challenging, but in a good way, help me to develop and think, how can I do this to make me feel a bit better, because I am feeling a bit down

Theme 4 Integration into life
Personalized P1 The questions that I found helpful, do I hear voices? do I trust other people, they were right on point, good questions to be answered by me, felt good because they were about me
Easy to use P1 It wasn't hard for me, I found it very easy, P1 It wasn't annoying to answer the questions, P1 Yes, it was helpful

Theme 5 uncertainty about self-monitoring with app
P6 It was useful to a certain degree
P12 A little
Integrating into life
P2 Sort of helpful, it was slightly irritating, didn't always work,
P3 Hard to adapt something new into your life, was good when I had it just didn't always have time
P3 Would want to phone a little bit more before I would be able to do it on my own, need to integrate it into my life a bit more, eg use a pen and paper
No new knowledge
P15 Not sure if the app helped notice the connection between work and paranoia
P15 Answered the questions without giving it much thought
P7 It wasn't that helpful because I already knew
Helping others
P9 Maybe it was helpful for the researchers, maybe it helps them in someway

Theme 6 Negative impact on mood
P2 always found that putting numbers to things doesn't always, I don't know, annoying to put mood and feelings into a number, when your mood isnt great it grates
P6 Started to get a bit stressed out with the phone, asking me silly questions, asking about killing myself I would answer no, but I would think what kind of questions are these, upsetting and a bit stressful
P8 It started making me feel like it was starting to pull me down, sometimes Id think what strategy goals could I do not to worry so much, pull myself together
P9 Don't think that it was helpful, sometimes it reminded me that I was frightened, but then just tried my best to answer the questions and just get on with it

Summary of Relationship between questionnaire and interview reports: Profile of Participants

In order to better profile any putative changes in insight captured by the mixed methods approach, the table below summarizes both the types of responses to the qualitative questions from section 3.5.1 and 3.5.2 and the quantitative questionnaire data from the SUMD-A sum total and the BCIS composite outcome scores for each of the 15 participants.

ID	Clinical Insight (2)	Cognitive Insight (2)	Self-monitoring helpful (2)	Level of understanding (2)	SUMD-A: Q1 (2)	% of protocol complete	BCIS	+/- BL (2)
1.00	Y	N	Y	Developed	1.00	71.7	4.00	L
2.00	Y	Emerging	Sometimes	N	1.00	4.16	12.00	H
3.00	Unrelated	Emerging	Sometimes	N	1.00	12.2	-2.00	L
4.00	Unrelated	Y	Y	Emerging	1.00	53.27	10.00	H
5.00	Y	Y	Y	Emerging	1.00	46.72	9.00	L
6.00	Y	Emerging	Y	N	1.00	57.73	11.00	H
7.00	Y	N	Sometimes	N	1.00	28.86	8.00	H
8.00	Unrelated	Y	N	Emerging	2.00	73.21	15.00	H
9.00	Y	Emerging	N	Emerging	2.00	96.4	8.00	H
10.00	Unrelated	Y	Y	Emerging	2.00	3.86	6.00	L
11.00	Y	Y	Y	Emerging	1.00	71.4	12.00	no change
12.00	N	Y	Sometimes	Emerging	1.00	37.79	-1.00	L
13.00	Y	Y	Y	Developed	2.00	96.4	7.00	H
14.00	N	Emerging	Y	Emerging	2.00	11.9	7.00	L
15.00	Y	N	Sometimes	Developed	1.00	17.8	12.00	H

Table 1 Coded responses to interview questions along with Question 1 SUMD outcome score, % of the ClinTouch app protocol complete, BCIS composite outcome score, + or – BCIS baseline score

From the above table it is evident that it is difficult to quantify the nature of clinical and cognitive insight using the quantitative questionnaires. In terms of the interview report, those who said 'no' to having a mental health disorder (n=2) had subsequently lower cognitive insight scores after self-monitoring and they had an emerging level of understanding. Interestingly those who had 'developed' codes in terms of a different understanding of their experiences, had worse outcome scores on the SUMD.

APPENDIX 9 Ethical Approval

NHS
Health Research Authority
National Research Ethics Service

NRES Committee West Midlands - South Birmingham
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4 Minshull Street
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M1 3DZ

Tel: 0161 625 7827
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19 December 2014

Charlotte Stockton
Project Manager
Institute of Brain, Behaviour & Mental Health
University of Manchester
Jean McFarlane Building, Room 3.320
Oxford Road
Manchester
M13 9PL

Dear Charlotte,

Study title:	**Proof of Concept (PoC) Feasibility Trial of ClinTouch-CareLoop Enhanced Management (CEM) versus Management As Usual (MAU) in people with psychosis**
REC reference:	**14/WM/0045**
Protocol number:	**N/A**
Amendment number:	**4**
Amendment date:	**21 November 2014**
IRAS project ID:	**146566**

The above amendment was reviewed by the Sub-Committee in correspondence.

Favourable opinion

Approval was sought to run qualitative interviews or focus groups with IT staff and to add additional questions for patients to study the effects of self-monitoring on metacognition in psychosis.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee asked the researchers to make the following changes to the IT staff Participant Information Sheet and consent form to include the following:

1. That the audio recording will be stored on a password protected device.
2. That the audio recording will be transcribed at the earliest possible occasion, but definitely no longer than 3 months after the recording is made.
3. That once the audio recording has been transcribed the original recording will be destroyed.

The researchers submitted revised documents and the Sub-Committee accepted them.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Interview schedules or topic guides for participants [Metacognition]	1	27 October 2014
Notice of Substantial Amendment (non-CTIMP)	4	21 November 2014
Participant consent form [IT Staff]	1	22 October 2014
Participant consent form [Metacognition]	1	14 November 2014
Participant information sheet (PIS) [Metacognition]	1	14 November 2014
Participant information sheet (PIS) [IT Staff - clean]	1.1	16 December 2014
Participant information sheet (PIS) [IT Staff - tracked]	1.1	16 December 2014
Research protocol or project proposal [tracked]	5	27 November 2014
Research protocol or project proposal [clean]	5	27 November 2014
Validated questionnaire [SUMD-A 2013 Additional file 1]		
Validated questionnaire [CHOICE, short version]		
Validated questionnaire [Beck Cognitive Insight Scale 2004]		

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

14/WM/0045: Please quote this number on all correspondence

Yours sincerely

On behalf of
Professor Simon Bowman
Chair

E-mail: nrescommittee.westmidlands-southbirmingham@nhs.net

Enclosures: List of names and professions of members who took part in the review

Copy to: Ms Lisa Dowell, Manchester Mental Health & Social Care NHS Trust
Professor Shon Lewis, University of Manchester
Dr Andy Mee, Manchester Mental Health and Social Care Trust

NHS
Health Research Authority

NRES Committee West Midlands - South Birmingham
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NG1 6FS

Tel: 0115 883 9428

11 May 2015

Dr Andy Mee
Manchester Mental Health and Social Care Trust
Rawnsley Building
Manchester Royal Infirmary Oxford Road
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Dear Dr Mee

Study title:	**Proof of Concept (PoC) Feasibility Trial of ClinTouch-CareLoop Enhanced Management (CEM) versus Management As Usual (MAU) in people with psychosis**
REC reference:	**14/WM/0045**
Protocol number:	**N/A**
Amendment number:	**SA6**
Amendment date:	**05 May 2015**
IRAS project ID:	**146566**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP) [Signed by Professor Shon Lewis, Uni of Manchester & Mrs Susan Dobson, MHSCT]		05 May 2015
Other [Metacognitive CareLoop Study Qualitative Questions: 12 week Outcome interview]	1	22 April 2015
Participant consent form [Tracked & Clean]	2.0	17 April 2015
Participant information sheet (PIS) [Tracked & Clean]	2.0	17 May 2015
Research protocol or project proposal [Tracked & Clean]	6	20 April 2015

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Chapter 3: Service Related Project

Service users' perspectives on the SLaM ECT service: The development of a new service user questionnaire

Clare Killikelly, PhD

Supervised by:

Professor Dene Robertson
Dr Neil Hammond
Dr Andrew Mogg

Abstract

Aim: Along with assessing service users' satisfaction and acceptability of electroconvulsive therapy (ECT) this newly developed questionnaire includes specific measures of psychological factors such as control and empowerment.

Methods: We developed an in-depth questionnaire to collect information on service users' knowledge, experience, attitude and psychological empowerment after receiving a course of ECT treatment. This version of the questionnaire had 47 questions across 4 subscales and for the first time included psychologically informed questions on knowledge, consent, fear and powerlessness. Patients understanding of side effects and overall satisfaction with ECT was also examined.

Results: 17 service users were asked to complete the questionnaire as part of an audit of the SLaM NHS ECT service. Service users piloted the questionnaire and 10 agreed to completed the final version of the questionnaire. Service user's experiences are described in terms of four main psychological themes: understanding and knowledge, consent, fear, and powerlessness. Overall the majority of service users reported satisfaction with their experience of the ECT service (e.g. 50% of service users would recommend to family or friends). However, it was also found that psychological processes such as empowerment might be important factors that shape an individual's experience and attitude towards ECT (e.g. 60% frightened or slightly frightened by the procedure).

Conclusions: The evaluation and feedback from the psychologically based patient experience of ECT may improve shared knowledge, access and understanding of ECT as a therapeutic option.

Key words: patient experience questionnaire, psychology, ECT

Chapter 3 Table of Contents

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1. Introduction

Electroconvulsive therapy is found to be one of the most effective short term treatments for severe depression, perhaps even more effective than pharmacotherapy (Tharyan & Adams, 2005; Van der Wurff, Stek, Hoogendijk, & Beekman, 2003). ECT may be particularly effective for people with late life depression as there is a lack of side effects (older adults are more prone to the side effects of anti-depressant medication) and no evidence of neural or physiological harm (Van der Wurff et al., 2003). Despite strong evidence for the efficacy of ECT, it remains a contentious treatment option, potentially due to lack of shared knowledge among the general public, clinicians and service users in terms of the current treatment process and therapeutic effects.

1.1 ECT evidence base and application

ECT was first introduced as a treatment for neuropsychiatric disorders in the 1930's. It involves the administration of a brief electric current to the head to artificially induce a tonic/clonic convulsion. Since the 1930s the procedure of administering ECT has been modified to improve safety and effectiveness. Thorough research has guided the placement of electrodes, the dosage and type of electrical waveform used and the frequency of administration. Service users are now put under general anesthetic and are usually prescribed a course of 6-12 treatments where they receive 2 treatments a week (Greenhalgh, Knight, Hind, Beverley, & Walters, 2005).

Over the last 20 years a series of robust, well designed studies have confirmed the efficacy and safety of ECT as a treatment for depression (Daly et al., 2001; Max Fink et al., 2007; McCall, 2004; Rasmussen, Knapp, et al., 2007; Rasmussen, Mueller, et al., 2007; Scott, 1993). Several systematic reviews and meta-analysis by leading international collaborators have also provided strong evidence for the efficacy of ECT (Scott, 1993; Tharyan & Adams, 2005; The UK ECT Group, 2003). In 2003 the UK ECT group published a highly influential review of the efficacy and safety of ECT in the treatment of severe depressive illness. They reviewed six randomized controlled

studies which found that real ECT (ECT with electrical current) was more effective than sham ECT (no electrical current applied) and 18 trials with 1144 participants found that ECT was significantly more effective than medication.

In 2005 Cochrane Review published a review of ECT for schizophrenia. They reviewed 26 studies and pooled data from 798 participants. They found that when compared with sham ECT or placebo, real ECT was more effective. The data also indicated lesser rates of relapse following real ECT and higher likelihood of being discharged from hospital after a course of ECT. They found some evidence to suggest that antipsychotic medication in combination with continuation or maintenance ECT treatment may be more beneficial than medication alone for people with schizophrenia. The UK NICE guidelines for ECT (NICE, 2009) are detailed and are based on evidence from a 2003 (updated 2009) Cochrane review and a commissioned systematic review from the department of health. NICE guidelines suggest that ECT should only be used for the following conditions; severe depressive illness, severe mania and catatonia. Although there is strong evidence for the effectiveness of ECT for treatment of depression and schizophrenia, there may be some patient groups that benefit more than others from ECT treatment.

Older Adults and ECT

The Maudsley and Bethlem ECT services treat patients of all ages, however older adults are significantly represented. For this service evaluation project more than 60% of the patients consenting to take part were over the age of 50. Depression is a common and debilitating disorder in older adults which can lead to increased disability and mortality (Van der Wurff et al., 2003). 12.5% of older adults suffer from a depressive disorder and 2% of adults age 60 and over experience major depressive disorder. Although life events, physical health , personality are contributors to risk factors for depression in the elderly biological factors are increasingly thought to be involved, for example, hyperactivity of the hypothalamic-pituitary-adrenocoritcal (HPA) system. This may be an important biological risk factor for the etiology of depression in the elderly (Van der Wurff et al., 2003).

Treatment for depression in older adults using pharmacotherapy is found to less effective for several reasons (1) increased physical illness and (2) increased medication use make older adults more likely to experience side effects of anti depressant medication (3) older adults with depression may have cerebral changes that may also mediate the effectiveness of antidepressant medication (Haines & Katona, 1992; Katona, 2001; Van der Wurff et al., 2003).

Biological risk factors and intolerance to antidepressant medication may be two main reasons that ECT is shown to be effective particularly for older adults. A higher proportion of older adults receive ECT when compared with younger adults with the same presentation (Plakiotis, George, & O'Connor, 2014). In 2003 Cochrane Review published a review of ECT for the depressed elderly (Van der Wurff et al., 2003). They reviewed 4 randomized control trials of the efficacy of ECT in older adults and found that only one study with 35 participants found that 'real' ECT was more effective than sham ECT. They suggested that a well designed RCT study needed to be conducted. Subsequently several studies have reported that ECT is particularly effective in older adults. Mitchell & Subramaniam, (2005) reviewed treatment of young-old adults (65+ years old) and old-old adults (80+ years old). They found several studies confirming that ECT in old-old adults was an effective treatment for depression. For example O'Connor et al 2001 found that younger service users did not response as well to ECT treatment as older service users. This is also confirmed by Wilkinson, Anderson, & Peters, (1993) who concluded that those service users over the age of 65 benefited more from ECT treatment. Tew et al., (1999) found that those under age 59 experienced less remission rates (54%) compared to 60-74 year olds (73%).

Over the years several studies have repeatedly confirmed the effectiveness of ECT for treating depression in older adults (Benbow, 1991; Cattan et al., 1990; O'Connor, Gardner, Eppingstall, & Tofler, 2010). However there are concerns about some of the side effects of ECT, particularly for older adults who have cognitive impairment (Dybedal, Tanum, Sundet, & Bjølseth, 2015). Post ECT side effects can include retrograde and anterograde amnesia and post treatment confusion (Bjølseth et al., 2015; Kellner et al., 2010; Kessler et al., 2014). However a meta-analysis by Semkovska & McLoughlin (2010) found that anterograde amnesia resolves after 15 days.

Retrograde amnesia may be permanent for both personal events and world events, however there is still not a consensus in the literature (Ingram, Saling, & Schweitzer, 2008; Kessler et al., 2014; McCall, Dunn, & Kellner, 2000; Sackeim, 2000; Semkovska & McLoughlin, 2013). Two recent studies have confirmed that there is no long term cognitive impairment post ECT (Fernie, Bennett, Currie, Perrin, & Reid, 2014; Maric et al., 2015).

Although side effects of ECT are a remaining concern for some professionals, others suggest that the amnesia found post ECT is similar to the effects of medications and to cognitive difficulties commonly found in those severely depressed (Fink, 2001). Indeed some professionals have expressed concern and confusion as to why ECT is not more widely used and is only considered a 'last resort' treatment (Fink, 2000). Fink even suggested that by not considering ECT more widely, clinicians are failing to provide a duty of care. To date research has focused on establishing and re-establishing the safety and effectiveness of ECT, however it seems that clinical effectiveness is not the only measure of ECTs acceptability. An area that is gaining interest is service users' experience of ECT. Research into service users perspectives and experience of ECT may not only improve procedural aspects ECT but may also target barriers in public and professional opinion that prevent the wide spread acceptability of ECT as an affirmed alternative to medication.

1.2 Patient Experience and Satisfaction with ECT and Measuring Patient Experience

Despite several international reports expertly confirming the safety and efficacy of ECT it still remains a controversial treatment. In the 1950's ECT was subject to restrictions and even legal sanctions because of public and professional concerns over safety (Fink, 1991; Sterling, 2000). Some professionals argue that ECT is completely safe (Fink, 2000), while others maintain that it can cause significant and lasting brain damage (Sterling 2000). To date there has been no conclusive evidence that ECT increases the risk of mortality or that ECT can directly lead to lasting cognitive impairment (APA 2001). However there are studies confirming anterograde memory loss (Sackeim, 2000; Verwijk et al., 2012) and anecdotal reports of memory loss, cognitive difficulties after ECT treatment and overall negative experiences with ECT treatment (Ejaredar & Hagen, 2014; Rose, Fleischmann, Wykes, Leese, & Bindman, 2003)

In 2003 Rose et al., conducted a systematic review of service users' experience of ECT. They reported on 35 articles that examined service users' views after ECT treatment (26 studies by clinicians and 9 user led studies with service users collaborating with clinicians or independently). They sought to systematically review service users' perceived benefit of ECT and side effects including memory loss. They found that studies that were led by clinicians as opposed to service users had higher ratings of the benefit of ECT. Only 20-40% of participants in patient led studies reported ECT as 'helpful' whereas the Royal College of psychiatrists fact sheet says that 80% of service users are satisfied with ECT treatment. This could reflect how clinician based studies usually take place relatively soon after treatment (less instances of remission) and the use of less complex questionnaires. When more in depth questionnaires are used service users perspectives are found to be less straightforward and complex. Rose et al., (2003) argue that service users weigh the advantages and disadvantages of ECT treatment and are not necessarily for or against treatment. Previous questionnaires have not always provided an opportunity to capture the complexity of service users' experience.

Chakrabarti, Grover, & Rajagopal, (2010)recently conducted a systematic review of 75 studies examining service users' knowledge attitudes and experience of ECT. In total these studies report results from 6000 service users in 17 different countries. They collated evidence on service users' knowledge of ECT, experience of the procedure, side effects and overall satisfaction with treatment. One of their main findings was that service users have poor knowledge of ECT, in terms of procedure, purpose and side effects. Of the 13 studies assessing service users' knowledge of ECT 0% to 59% of service users had some knowledge of ECT. On average 66% of service users felt that they had not received enough explanation of the treatment prior to receiving ECT. They also found that service users were not satisfied with the procedure of establishing consent. In several instances service users reported perceived coercion for example in terms of feeling pressured into receiving ECT or not having the right to refuse (20%-35% of service users). Some suggest that service users go forward with ECT despite reservations because they trust their clinicians, others argue that a sense of powerlessness prevents them from objecting. Fear of ECT and the procedure of

receiving ECT have also been reported, with 47-75% of service users reporting feeling anxious before ECT treatment. Reports of adverse side effects suggest that memory impairment is the most common. 3-100% of service users report memory loss across the range of studies.

Several important themes emerge from studies of patients' perspectives of ECT treatment including; 1) service users feel that they have not received enough information about ECT in terms of side effects and risks 2) service users feel forced or coerced into receiving ECT 3) fear and anxiety about the process of ECT 4) memory loss as a distressing and common side of ECT. These 4 themes are important indicators of service users' satisfaction with ECT and could be areas to improve on in the ECT clinic. Several questionnaires have been developed that attempt to capture these 4 themes and these are discussed more below. One area that is often missing for patient satisfaction questionnaires are specific psychological factors that impact of service-users experience. Several authors (Ejaredar and Hagan, 2014; Chakrabarti et al., 2010) have noted that when patients are provided with the time and space to speak openly about their experience a more complex perspective of ECT is revealed.

1.3 Psychological Factors involved in ECT

A recent qualitative study analyzed the interviews of 9 women who had received treatment with ECT (Ejaredar and Hagen, 2014). In the qualitative analysis of the interviews four main themes emerged including; 1) he really didn't say much (relating to information about the ECT procedure) 2) Im going to be very upset with you (relating to feelings of pressure or coercion) 3) I was just desperate (relating to the vulnerability of giving informed consent when unwell) 4) it was like we were cattle (relating to the experience of waiting for the procedure). Overall the authors concluded that an in-depth qualitative analysis provided a very negative picture of individuals experienced with ECT treatment. The authors attributed this negative experience to lack of knowledge and lack of power of service users. They suggested that these are important constructs that were not considered throughout the treatment period.

Some authors have argued that the negative psychological aspects of ECT outweigh the short term benefit of treatment (Ejaredar & Hagen, 2014; Johnstone, 1999). Fisher et al., (2011) emphasizes the importance of service users having a clear understanding of ECT prior to treatment. Fear before ECT treatment is linked to lack of information and misinformation about ECT (Fisher, Johnstone, & Williamson, 2011). Those who feel fearful before receiving ECT are also more likely to have a negative experience of ECT (Fisher, 2012). Johnstone (1999) suggests that negative of experiences of ECT not only impact on the individual but also rupture trust in mental health professionals, reduce help seeking and impact on therapeutic relationships.

Fisher (2012) examined the psychological aspects of the experience ECT treatment. He explored the potential role for increased input and involvement from psychological professionals to support shared decision making and the experience of ECT. Fisher reviewed previous quantitative and qualitative accounts of service users experience with ECT and identified several areas of psychological focus; consent, fear, powerlessness, memory and identity. Fisher identified that service users' experience and perception of their treatment throughout the course of ECT can have a significant impact on their outcomes. He recommend that psychologists had an important role in improving the procedures of consent, assisting in formulating a shared understanding of the service users experience, and empowering service user to share their opinions and experiences of ECT.

There have also been qualitative and anecdotal reports of the positive effects and experience of ECT (Fisher et al., 2011; L. Morrison, 2009; Ng, 2009). In many accounts service users have highlighted clear benefits and minimal side effects. Morrison (2009) provides a detailed account of her experience and concludes that for her it is a preferred treatment option. A better understanding of the psychological factors that contributed positively in these cases could help guide procedure and shared understanding; for example services that ensure that patients are feeling comfortable and trust professionals with their care.

Exploration of the psychological factors impacting upon service users' experience of ECT has the potential to improve service users experience but also could help foster

the acceptability of ECT and strengthen the anecdotal and qualitative evidence base for practice.

1.4 The Service Issue: motivation for the SEP and design of the questionnaire

Service Need

At the Maudsley and Bethlem ECT clinics approximately 60% of service users are deemed to have capacity to give informed consent. For those deemed able to give consent NICE guidelines (2008) state: 'To help in the discussion, full and appropriate information about ECT should be given, including information about its potential risks and benefits, both general and specific to the individual.' However Rose et al (2003) highlighted that patient knowledge of the ECT procedure may not always be clear and accurate. In fact, providing this patient group with the appropriate knowledge and information about ECT may be particularly difficult due to the severity of depressive impairment prior to treatment and reports of significant memory loss during treatment. Therefore extra care and effort may be required to ensure that service users have understood and retained information about the ECT process. We therefore sought to develop a questionnaire that could assess service users' current knowledge of ECT and could also provide feedback for how to improve the service specifically in terms of providing service users with information about ECT and ensuring adequate knowledge sharing. Additionally as previously mentioned, a significant number of patients who are referred for ECT treatment are older adults. In previous surveys of patient experience of ECT the older adult experience has not been represented. For example the average age of participants in Rajagopal, Chakrabarti, & Grover, (2013) survey was 36 years (range 18-67), and Tang, Ungvari, & Chan, (2002) was 43.6 years (sd= +- 17.9). This service evaluation project sought to develop a survey that would be accessible and useable for older adults as well as younger.

The aim of the current project was two fold; firstly to develop an in depth questionnaire to assess service users experience and knowledge of ECT and second to pilot the questionnaire in terms of feasibility and utility in the ECT service as a measure of quality of care. Evidently several previous studies have examined service users' knowledge, experience and attitude towards ECT treatment. Most of these studies have used questionnaires or checklists, utilizing simple response categories that

perhaps fail to capture the complexity of the decision making process and experience. We sought to develop a questionnaire that was more in depth and detailed as described below.

Design of questionnaire

The design of the questionnaire could have a significant impact on the type of response that is given and the interpretation of these responses. For example Rose et al., (2003) found that reports of patient satisfaction depended on how a response was elicited. When designing a Patient satisfaction questionnaire Rose et al., (2003) reviewed and rated studies on the following characteristics; interval between treatment and interview, number of questions, complexity of interview, setting of interview and status of interviewer. Rose et al., (2003) rated the following surveys highly in terms of the above criteria; Freeman & Kendell, (1980), Rogers & Pilgrim, (1993), United Kingdom Advocacy Network (1995). Following these criteria we designed our questionnaire based on an updated version of (1) Freeman and Kendall's (1980) well-cited questionnaire; Rajagopal, Chakrabarti, Grover, & Khehra, (2012) and (2) Goodman, Krahn, & Smith, (1999) the Patient Satisfaction Survey (PSS). Rajagopals' updated 2012 questionnaire is one of the most in-depth questionnaires to explicitly collect information on service users' attitude, knowledge and experience of ECT. Additionally the original PSS (Goodman et al., 1999) has 44 questions across 5 subscales for overall satisfaction with ECT, satisfaction with results of ECT, education or information about ECT, satisfaction with staff and 'your feelings'. The PSS is found to have good reliability, high specificity and internal consistency (Rajagopol et al., 2013). We combined aspects of both questionnaires in order to capture satisfaction along with knowledge, attitude and experience of ECT.

We developed an ECT questionnaire that has several unique features. (1) Originally the questionnaire was designed to be administered before and after treatment. Service users' knowledge of the ECT process was to be reviewed and compared before and after ECT treatment and service users were to be asked to comment on their expectations and experience of treatment. (2) Very few studies have used a qualitative interview approach (Froede & Baldwin, 1999; Koopowitz, Chur-Hansen, Reid, & Blashki, 2003; Rajkumar, Saravanan, & Jacob; Rose, Fleischmann, & Wykes,

2009) and due to constraints in terms of the feasibility of conducting in depth interviews in the clinic environment we did not include a qualitative interview. However service users had the opportunity to comment openly on what they would improve about the service and what worked well. (3) We also incorporated some specific psychologically informed questions into this adapted questionnaire. We incorporated specific questions from the Empowerment scale (Rogers, Chamberlin, Ellison, & Crean, 1997) to assess service users' feelings of powerlessness and control throughout the experience. (4) Additionally in line with Rose et al., (2003) and Chakrabarti et al., (2010), the questionnaire was designed and administered by a psychologist from outside of the ECT service.

1.5 Service User Involvement

The "South London and Maudsley NHS Trust. (SLaM): Patient and Public Involvement Policy, Guiding Principles and Resource Pack", presents guidelines for assuring service user involvement including the following:

1. To increasingly involve and consult with service users regarding the service provision/ care they receive.

2. A policy to involve and consult with service users in the planning and provision of services within SLAM and in any proposed changes to services.

The project has prioritized service user involvement in the following importantly ways. Firstly the aim of the project is to provide service users of all ages, specifically older adults aged 65+, with the opportunity to voice their individual experiences of the ECT service, so as to ensure quality and acceptability of the service. Secondly this service evaluation project will assess service users' access to information and understanding of the information provided that explains the ECT process and experience. Thirdly throughout the development and assessment of the questionnaire service users were consulted. The questionnaire was initially piloted on two service users who gave feedback on the length and content of the questionnaire.

1.6 Aims and Objectives

The aim of the service evaluation project is to develop and pilot a new psychologically informed service user experienced questionnaire. This questionnaire focuses specifically on including questions on the process of consent and knowledge of service users, inclusion of the older adult service user, and inclusion of psychological questions of control and empowerment.

Along with developing and piloting a new service experience questionnaire, a secondary aim of the current service evaluation project is to review participants' experiences of ECT treatment at the Maudsley and Bethlem ECT clinics. Information acquired from the service evaluation project will be used to further develop the ECT service, for example improving service users' access to information about ECT and improving their experience during the treatment. Additionally a better understanding of ECT may lead to improved patient experience which in turn may improve shared knowledge, access and understanding of ECT as a therapeutic option.

2. Methodology

The questionnaire was designed to provide a comprehensive picture of service users' experience of the ECT clinic. This questionnaire is longer and more in depth than other similar questionnaires, and therefore provides rich and detailed data from a smaller number of participants who consented to complete the questionnaire. These results will inform the development of a shorter user friendly questionnaire that could be administered to service users routinely.

2.1 Sample

The current sample of service users were referred to the project by psychiatrists at the Maudsley and Bethlem ECT clinics between May 2014 and May 2015. 17 service users were referred to complete the questionnaire and 10 service users subsequently agreed to participate and had capacity to consent to answer the questionnaires. Service users who were referred met the following criteria; recently completed a series of ECT treatment, capacity to consent to completing the questionnaire, diagnosis of mental

health disorder, above age 18. The demographic details of the participating service users are detailed in *Table 1* in section 3.2 below. Capacity to consent to treatment was assessed by the referring psychiatrist. For a patient who would like to participate in the audit but did not consent to treatment, specific capacity to participate in the audit was assessed separately by a team psychiatrist. Additionally a statement was included on the questionnaire to clarify that participating or not participating in this project would not affect the service users' treatment in any way. Within 1 week of completing ECT treatment service users were asked to fill out a brief questionnaire about their experience of the service and had the opportunity to comment openly about the negative and positive aspects of their experience with the service.

2.2 Procedure

This service evaluation project took part in two phases. The first was the development of the questionnaire. The second was the administration and assessment of the newly developed questionnaire.

2.2.1 Development of the questionnaire

The development of questionnaire took part in several stages. (1) The first step was to decide on a questionnaire and to amend the questionnaire to meet the needs of the service. This was done through a series of discussions with the teams' psychiatrists, nurses, ward nurses and psychologists. In the initial plans for the questionnaire we had hoped to have two versions of the questionnaire; pre treatment questions and post treatment questions (see Appendix 1). However after piloting it was determined that many service users would be too unwell to complete the questionnaire before treatment. Therefore a post treatment questionnaire was developed and contained a wide breadth of questions.

(2) The questionnaire was initially piloted on 2 service users. Service users provided verbal feedback on the length of the questionnaire, the clarity of the questions, and the content of the questions. All participants found the questionnaire to be acceptable to complete post treatment. They stated that it was not too long and was clear to understand.

(3) The questionnaire was piloted and assessed on 10 consenting service users in the main pilot described below.

(4) After the main pilot the questionnaire was refined and shortened with the aim of being acceptable for use in the clinic, with the feedback from service users and the clinical team.

2.2.2 Administration and main pilot to assess the questionnaire

The questionnaire was administered to referred service users in person by the author or by a member of the nursing staff. If the patient had been discharged from the service before receiving the questionnaire a telephone interview was conducted. Feasibility and utility of the questionnaire was assessed by administering the questionnaire to 10 consenting service users.

Data was grouped by different subscales of the questionnaire and the descriptive statistics were calculated using excel. These will be presented in detail in Section 3. When the qualitative sections of the questionnaires were filled out important themes are discussed in section 3.3 and full quotations are found in Appendix 2.

2.3 Measure

As previously mentioned the aim of this questionnaire was to obtain detailed and in depth information about service users experience with the intention to refine and shorten the questionnaire for practical and accessible use in the service. The content and duration of the questionnaires was decided with clinicians and with service user feedback. This specific measure was developed with permission based on Rajagopal et al's 2013 Patient Satisfaction Survey (PSS). We amended and built on this measure to include specific psychological factors as recommended by Fisher (2012). This resulted in a questionnaire of with a total of 47 questions on a three point scale divided into 4 subsections; Knowledge and information about ECT; Experience of the ECT procedure; the process of consent; empowerment. The questions were based on Rajagopal et al.,'s 2013 PSS which included questions that were specifically designed to be unambiguous, easily understandable and free of value laden terms. We also included

a space where participants could write additional comments. On average the questionnaire took approximately 20 minutes to complete.

2.4 Ethical Approval

Ethical approval was granted by South London and Maudsley Clinical Governance and Audit committee for the Mental Health of Older Adults and Dementia CAG on May 12th 2014. For details please see Appendix 3.

3. Results

3.1 Participant Information

During the period of recruitment (May 2014 until May 2015) there were 38 service users referred to the Bethlem and Maudsley ECT clinics. Due to the nature and severity of mental illness in this population only those well enough to consent to complete the questionnaire were referred to the project therefore resulting in a small sample size. Of the 38 service users treated by the ECT service 17 were referred to complete the questionnaire, of which 10 consented to complete the questionnaire. See Table 1 for the demographic and clinical profile of the service users. The majority of the service users who consented to completing the questionnaire were middle age females with a diagnosis of psychosis or psychosis related disorder. This also reflected the gender statistics of referrals to the ECT service (24 females and 14 males). The average age of respondents was 56.9 (range: 28 to 81 years) with 60% of service users over age 50. The majority of those who completed the questionnaire had also had previous courses of ECT treatment (average 2.1 courses of ECT). This ranged from 1 previous to 4 previous courses of ECT.

Table 1 Demographic and Clinical Profile of the Service users

Demographic and Clinical Profile of Service users	**(%) (N=10)**
Gender, Males	40 (4/10)
Age (mean)	56.96
Primary Diagnosis	
Schizophrenia/ other psychotic disorders	60 (6/10)
Depressive Disorders	40 (4/10)

Previous treatment with ECT	
Service users who had previously received ECT	60 (6/10)
Service users who had not received ECT previously	40 (4/10)
Average time since last ECT, days (mean)	18.8 (1 outlier)
Number of courses of ECT (mean)	2.1

On average service users completed the questionnaire 18.8 days after receiving the last ECT treatment session. One patient completed the questionnaire 48 weeks after receiving the last course of ECT treatment. These assessment time frames are in line with those assessed by Rajagopal et al (2013).

3.2 Descriptive Statistics

The results are presented as tables based on frequency counts and percentage scores for each response option. Each of the four subscales of the questionnaire are presented below.

Table 2 Subscale 1 Knowledge and information about ECT

Subscale 1: Knowledge and Information about ECT				
		Service users' Response: N		
Questions: Procedure		Correct	Incorrect	Don't know
1.	During ECT, anesthetic /other medications are used	9	0	1
2.	How often is ECT given per week?	10	0	0
3.	How many ECTs do most service users require in one course?	4	1	5
4.	Where is the current applied?	6	1	3
5.	Who can administer ECT?	7	0	3
6.	What is ECT?	7	1	2
7.	Certain investigations are needed before ECT	4	1	5
8.	How long is the current applied?	4	1	5
9.	How is ECT given?	7	0	3
10.	ECT is often used to …	7	1	2
Questions: Side effects		Correct	Incorrect	Don't know
11.	Use of ECT leads to temporary impairment of memory	8	0	2
12.	Use of ECT leads to permanent loss of memory	5	1	4
13.	ECT results in permanent damage to brain	4	0	6
14.	ECT can damage other body-parts permanently	5	0	5
15.	During the ECT chances of death are very	7	1	2

	high			
16.	Headache is a common side effect of ECT	1	5	4
17.	Most of service users receiving ECT develop epilepsy later	4	0	6

In terms of knowledge and information about the procedure ECT 65% of responses were correct (see figure 1). Questions 1 (During ECT, anaesthetic /other medications are used) and 2 (How often is ECT given per week?) had the highest number of correct responses, while questions 3 (How many ECTs do most service users require in one course?) 7 (Certain investigations are needed before ECT) and 8 (How long is the current applied?) had the lowest number of correct responses. In terms of side effects (see figure 2), only 48.5% of responses were correct. It was found that over 50% of respondents replied 'Don't know' to question 13 (ECT results in permanent damage to brain), 14 (ECT can damage other body-parts permanently) and 17 (Most of service users receiving ECT develop epilepsy later). Only 1 participant correctly identified that headache is a common side effect of ECT.

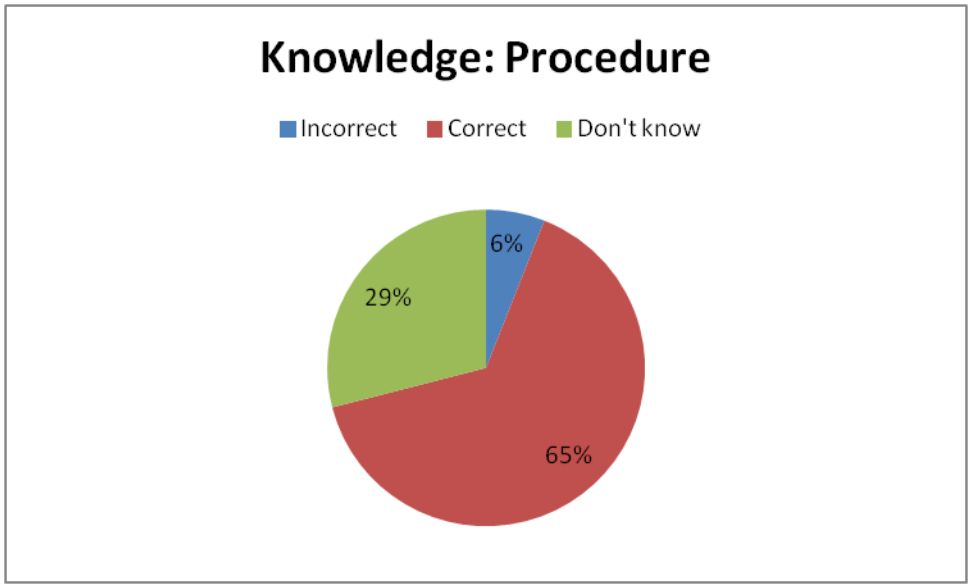

Figure 1 Knowledge: procedure, questions 1-10

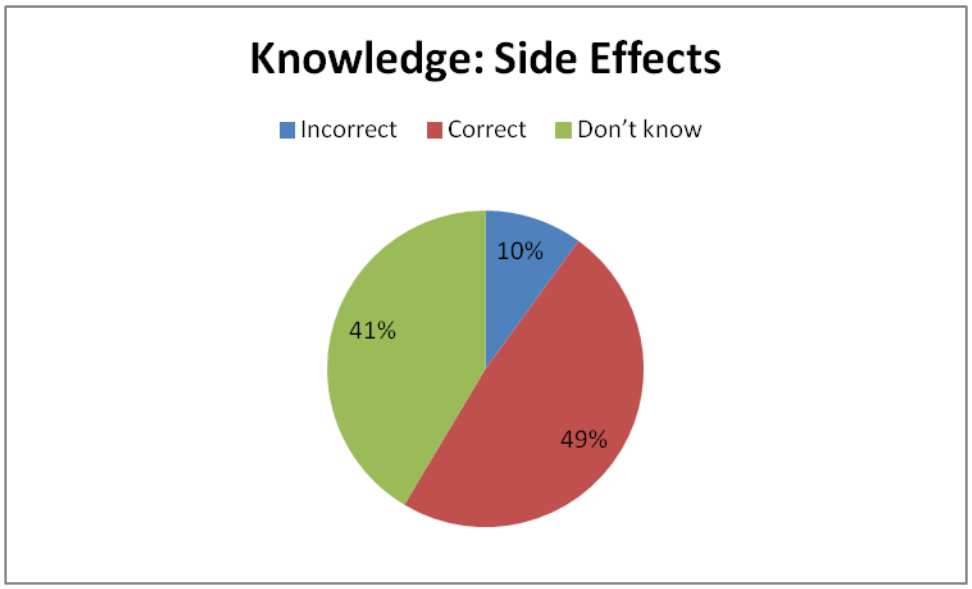

Figure 2 Knowledge: side effects, questions 11-17

Table 3 Subscale 2 Experience of ECT

Subscale 2: Experience of ECT

		Service users' Response: N		
Questions		**Positive Experience**	**Negative Experience**	**Undecided**
1.	How helpful was ECT in your case?	6	2	2
2.	Does your experience suggest that ECT is better than drugs?	6	0	4
3.	Experience of night prior to the day of ECT	5	0	5
4.	Experience of waiting for your turn for ECT	4	2	4
5.	Experience of procedure of ECT	4	1	5
6.	Experience after waking up after receiving ECT	4	5	1
7.	Experience with any long term side effects	4	1	5
8.	How do you rate our overall experience with ECT?	3	1	6
9.	How frightening or upsetting was ECT compared to what you expected?	4	6	0
10.	How do you compare receiving ECT to visiting a dentist?	2	3	5
11.	Did ECT upset you so much that you would be reluctant to accept it again?	7	2	1
12.	Considering the effect of ECT, was it delayed in your case?	1	3	6
13.	How was your experience with the process of informed consent?	3	0	7
14.	Do you feel you received sufficient information regarding ECT prior to treatment?	5	3	2
15.	Did you ever feel you were being forced into	6	2	2

	accepting ECT?			
16.	Why did you agree to have ECT?	(Illness too long) 3	(Too severe) 2	Drs advice 4
17.	How likely are you to recommend our service to friends and family if they needed similar care or treatment? (scale from 0-5)	5 (all responded with 'likely')	1	4

For subscale 2 'Experience of ECT' the 'positive experience' category reflects that the respondent answered the question to indicate that they had a positive experience of the service, whereas the 'negative experience' category indicates that the respondent answered the question to indicate they had a negative experience of the service. In terms of positive experience more than 70% of participants responded 'No' to the following; Question 11 (Did ECT upset you so much that you would be reluctant to accept it again?). 60% of respondents said that they were not forced into accepting ECT. 60% of respondents said that they found ECT to be helpful and found ECT to be more helpful than medication. 50% of respondents said that they were likely to recommend the service to friends of family if they needed similar care. In terms of ambivalence or negative experiences, when asked to rate their overall experience with ECT, 60% of respondents were undecided. On question 9 (How frightening or upsetting was ECT compared to what you expected?) responses indicating very frightening and slightly frightening are pooled under the 'negative experience' responses to indicate that 60% of responses were in this category. 60% of respondents indicated that they did not know if the effect of ECT was delayed and 70% of respondents were undecided about the process of informed consent.

The following pie chart in figure 3 summarizes the proportion of negative, positive and ambivalent responses for questions 1-15 of this subscale.

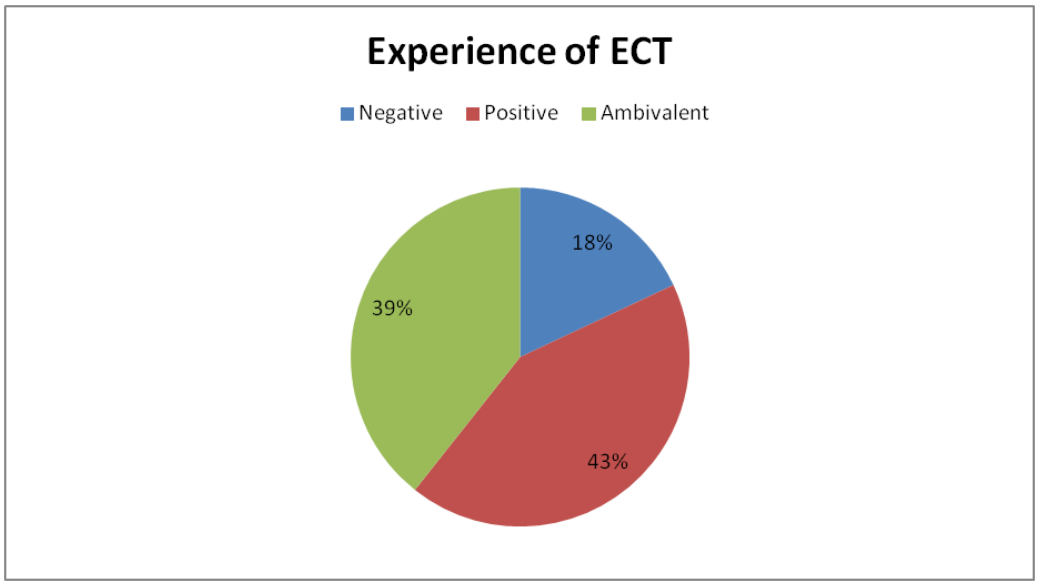

Figure 3 Experience of ECT, proportion of responses. Questions 1-15 of the experience subscale were included in this pie chart.

Table 4 Subscale 3 The process of consent

Subscale 3: The process of consent

		Service users' Response: N		
Questions		**Yes**	**No**	**Don't know**
1.	Who discussed consent with you?	(Dr) 7	(Nurse) 0	3
2.	Did you sign a form giving consent?	5	3	2
3.	Were you in distress when giving consent?	1	5	4
4.	Did you feel supported and listened to while giving consent?	6	1	3
5.	Would you have preferred additional support and advice prior to giving consent?	5	3	2

In terms of the process of consent 60% of respondents said 'yes' to feeling supported and listened to while giving consent. 50% indicated that they would like additional support or advice prior to giving consent (question 5) however 50% of respondents indicated 'no' when asked if they were in distress prior to giving consent.

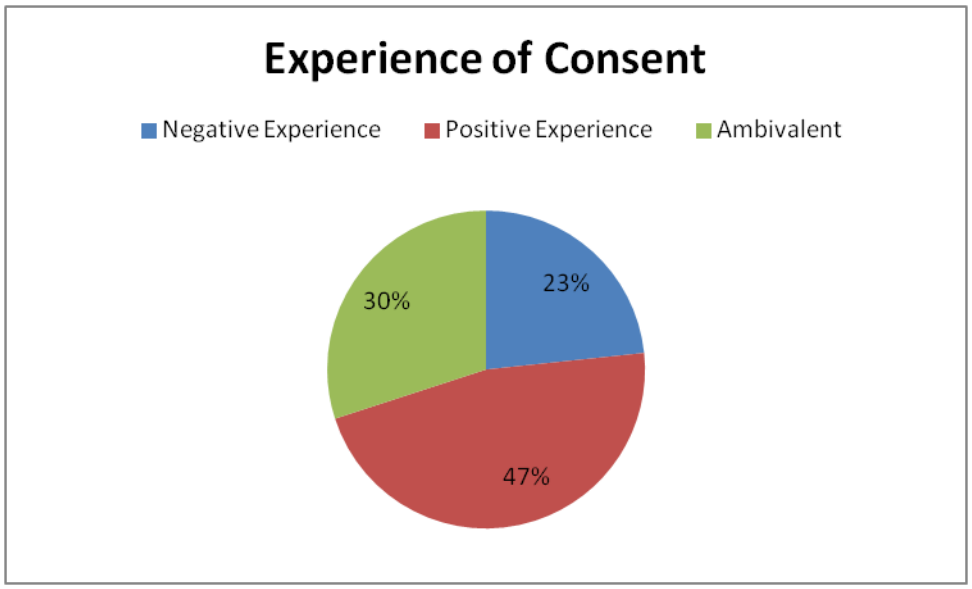

Figure 4 Consent: based on the last 3 questions of the consent subscale, 3 and 5 were reverse scored.

Table 5 Subscale 4 Empowerment

Subscale 4: Empowerment

		Service users' Response: (N) %		
Questions		**Yes**	**No**	**Don't know**
1.	Did you experience feelings of powerlessness?	4	3	3
2.	Did you experience feelings of humiliation?	0	9	1
3.	Did you experience feelings of lack of control?	3	4	3
4.	If recommended, I would receive ECT treatment again	6	1	3
5.	In the future I would prefer psychological therapy over ECT	0	5	5
6.	Did you feel involved in making decisions about your care?	6	3	1
7.	Were you given a choice of options other than ECT?	3	1	6
8.	Did you feel alone before during or after the ECT process?	2	6	2

In terms of experience of empowerment 40% of respondents indicated that they did experience feelings of powerlessness. 50% of participants responded 'don't know' when asked if they would prefer psychological therapy over ECT. 60% of respondents indicated that they did not know if they were given a choice of options other than ECT. 90% of respondents did not experience humiliation. 60% indicated that they would

receive ECT again. 60% indicated that they did not feel alone during the ECT process and felt involved in making decisions about their care.

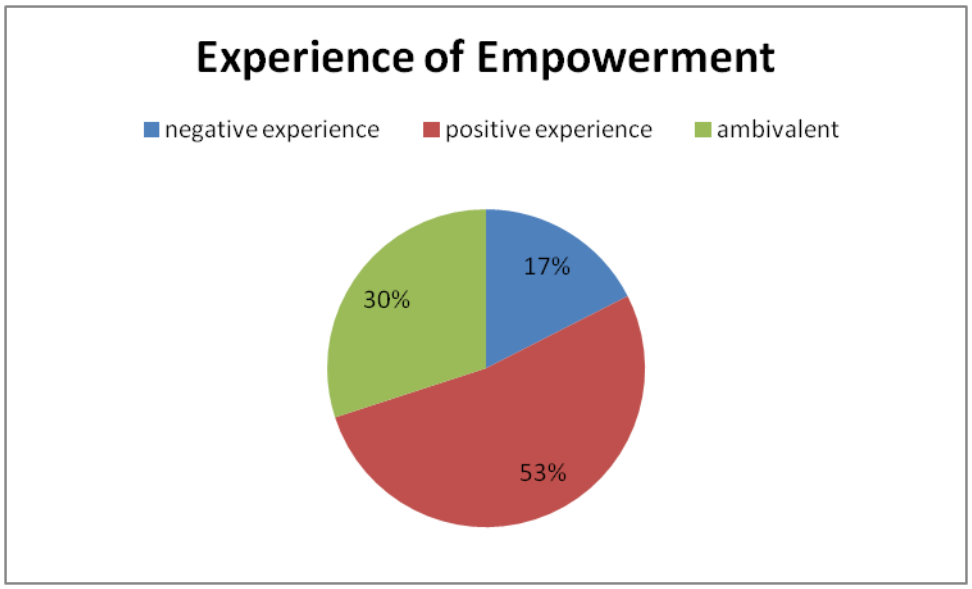

Figure 5 Experience of Empowerment. All 8 questions were included in this pie chart, with questions 1,2,3, 5 and 8 reverse scored.

3.3 Summary of Qualitative Feedback

At the end of each questionnaires service users were asked to provide open feedback about their experience. They were asked if there was anything else they would like to comment on or anything specific that they found positive or negative about the experience. Of the 10 respondents 6 chose to write in the additional comments section. This indicates that the majority of service users would provide qualitative feedback about their experience if given the option. A full transcript of the feedback is presented in Appendix 2. The responses were both positive and negative for example

'I don't want to have no more ECT, I want to concentrate on depot injection.'

'Yes it was beneficial for me, got rid of my depression. I didn't feel isolated anymore'

Responses centred around themes of (1) requesting information (2) ECT vs medication (3) positive benefit (4) uncertain long term benefit.

4. Discussion

In summary, we developed an in-depth questionnaire to collect information on service users' knowledge, experience, attitude and psychological empowerment after receiving a course of ECT treatment. This version of the questionnaire had 47 questions across 4 subscales. 10 service users consented to complete the questionnaire. Overall the results provide insight that will inform current practice in the service and will the assist with the development of a shorter, user friendly, psychologically informed questionnaire.

4.1 Experience of the Service: Results from the Questionnaire

Overall the majority of service users reported satisfaction with their experience of the ECT service. Two questions in particular captured patient satisfaction; from subscale 2 question 11 'Did ECT upset you so much that you would be reluctant to accept it again?' 70% of respondents answered no, indicating that they would receive ECT again; and question 17 'How likely are you to recommend our service to friends and family if they needed similar care or treatment?' 50% of respondents said that they were likely to recommend the service. However for question 8: 'How do you rate our overall experience with ECT?' only 30% of respondents indicated a positive experience with the majority (60%) indicating ambivalence. This is in line with what Rose et al., (2003) report that service users' experience of ECT is complex and is not necessarily good or bad. However it also indicates that there are some improvements that could be made in the 'overall' experience of the ECT service.

Themes

Researchers, clinicians and service users have identified several themes that impact upon their experience of ECT (Chakrabart et al,. 2010; Fisher et al., 2012; Rose et al., 2003). As reviewed above, knowledge and information about ECT, the process of consent, fear and anxiety and other psychological process such as empowerment are

all important factors that shape an individual's experience and attitude towards ECT. The results of this questionnaire highlight some interesting findings in terms of each of these themes and confirm that these are important areas of consideration for the ECT service.

Knowledge

The results of this questionnaire confirm that shared knowledge and information about ECT is still an area that can be improved upon. Service users had better knowledge of procedure (65% correct) than side effects (49% correct). In terms of procedure only 29% did not know the correct answer and only 6% responded incorrectly. In terms of side effects 41% of service users did not know the answer and only 10% responded incorrectly. It seems that service users are poorly informed, particularly in terms of side effects. These findings are in line with previous reports. Rose et al., (2005) found that about 50% of service users felt they had enough information to make an informed decision. Misinformation and stigma around the side effects of ECT can have a negative effect of service user experience. Fisher et al., (2011) found that service users' fear of ECT is linked to their prior, perhaps, incorrect knowledge of ECT. Sharing more information about side-effects of ECT particularly in terms of worries about brain damage or permanent memory loss, may help to clarify patients concerns and resolve any unfounded fears.

Consent

The process of consent was overall positive. 60% of service users indicated that they felt supported and listened to while giving consent to treatment. 50% of service users also said that they had received enough information about ECT prior to giving consent. This in line with previous accounts, for example, Fisher et al., (2011) and Rose et al., (2005) found that 50% of patients felt they had received enough information prior to treatment. Fisher et al., (2012) suggested that rates of coercion seemed to increase overtime, however in this current report, when service users were asked if they felt forced into receiving ECT 60% indicated that they had had a positive experience and had not been forced or coerced. There is the potential to improve the process of consent. For example 50% of service users responded positively to the suggestion of

providing additional support and advice prior to giving consent. Additionally 70% of service users said that they were ambivalent about the process of informed consent. Only one service user said that they were in distress while giving consent and the majority (50%) said that they were not.

Fear

Service users did indicate some fear or anxiety about the overall experience of ECT. When asked if ECT was as frightening as what they expected 60% answered that it was either slightly frightening or very frightening. Chakrabarti et al (2010) also reported that over 50% of service users experienced some fear or anxiety throughout ECT treatment. 30% said that it was worse than visiting a dentist and 50% rated the experience of waking up after ECT as negative. However 70% said that it did not upset them so much that they would not accept it again. When asked to rate the procedure of ECT, waiting for ECT and waking up after ECT 40% reported a positive experience. These ratings are not dissimilar from other procedures. For example Lu et al., (2011) found that 69% of people in treatment for psychosis met criteria for PTSD, with many people reporting a frightening treatment experience that was related to feelings of having no control.

Psychological factors: Empowerment

When asked if service users experienced feelings of powerlessness 40% said yes, 30% said no and 30% were undecided. This powerlessness perhaps comes from feelings of lack of control (30%) and feelings of being alone (20%). However no service users had any feelings of humiliation and 60% said that they felt involved in making decisions about their care and confirmed that they would receive ECT again if required. Fisher et al., (2011) found similarly mixed results. Some participants reported feelings of powerlessness while others felt supported and content with the treatment procedure. Fisher (2012) suggests that service users may experience feelings of powerlessness at different times throughout the treatment process. Johnstone (1999) found that in her study feelings of humiliation and worthlessness during ECT were related to early life experiences of feeling weak and vulnerable. It is evident that service users do have feelings of lack of control and powerlessness and it would be helpful to further explore

where these come from and what could be done to reduce them. This could be an important role for psychological work.

4.2 Service Implications and Recommendations

Experience of the service: Summary

In summary there were several indicators of positive practice in the ECT service. These should be highlighted and reinforced. There were a few areas of negative feedback that could perhaps be further explored and considered for improvement. Both the positive and negative feedback are outlined in the table 6 below.

Table 6 Summary of feedback

Theme	**Positive Feedback**	**Negative Feedback**
Overall	50% of service users would recommend to family or friends 60% confirmed that they would receive ECT again if recommended	60% ambivalent about the experience of ECT
Knowledge	65% had correct knowledge about ECT procedure	51% did not know correct answers about side effects
Consent	60% felt supported during the process of consent 60% did not feel forced into consenting	70% were ambivalent about the process of consent 50% would like additional guidance prior to consenting
Fear	70% were not so frightened that they would refuse ECT	60% frightened or slightly frightened by the procedure 50% negative experience waking up after ECT
Powerlessness	None experienced humiliation 60% felt involved in decision making process	40% had feelings of powerlessness

Based in this information the following recommendations are made to the ECT service. In terms of knowledge and information, if possible more time could be allocated to the initial discussion about ECT and perhaps a detailed leaflet with explanations of side effects could be offered. Given that the majority of the patient group is comprised of older adults perhaps clear audio visual aids could also be considered. For example Chakrabarti et al., (2010) recommend that information is presented to service users in a graded manner and repeated several times until comprehensive is ensured. They

also suggest that there is enough time in the pretreatment meeting to ensure that service users have processed and retained the information. More time for discussion during the initial meeting could also provide service users with a space to discuss any worries and fears and this may help service users to feel empowered and involved in their care.

In order to provide additional guidance during the process of consent, additional support could be offered by inviting a relative or other members of the patients care team to support the patient during the initial consultation and throughout the procedure to ensure that questions about procedure and consent are asked and can be revisited outside of the clinic. A concise but informative information pack could be given to patients and their carers to ensure that clear information is given and patients have the opportunity to re-examine the information at their own pace.

Finally as mentioned in more detail below, patients could be offered the opportunity to speak with a psychologist about their feelings towards treatment. A psychologist could provide a space for the patient to discuss their fears and anxieties about treatment. A psychologist may also over clarification and reassurance about the procedure and to explore expectations. A shared formulation could also be developed that may help the patient and the team to have a clear understanding of the reasons for treatment and expectations.

Further development of the questionnaire; recommendations

The aim of this project was to pilot a newly developed in-depth questionnaire that could be further refined for use in the ECT service. This questionnaire has some advantages over previously developed questionnaires; however there were also some difficulties. A refined version of the questionnaire might include some of the following recommendations. See Appendix 4 for a draft version.

This pilot questionnaire was specifically developed with the following features; (1) it focused on 4 important themes with several questions for each in order to get a wide breadth of patient feedback on the areas of knowledge and information, consent, side effects, fear and anxiety and powerlessness,(2) it is the first ECT patient satisfaction

questionnaire to include questions about empowerment, (3) it includes the Friends and family question (an NHS service wide feedback measure) (Chakrabarti et al., 2010; Fisher, 2012) and (4) It was administered by a practitioner from outside of the service who did not have the status of Dr or medical professional (trainee). It therefore aimed to provide in depth unbiased account of patients experiences. (5) The questionnaire was administered to service users with different presentations (depression, psychosis) and different ages (range from 28-81 years).

However there were some disadvantages to this questionnaire. One of the main difficulties with this long questionnaire was the impractically of using in the clinic environment. There are 3 main reasons why this was difficult. Firstly, it was difficult to get feedback from servicer users. Many service users who are referred for ECT are extremely unwell to the point where they may not be able to move or speak. It is therefore extremely difficult to ask them to complete a long questionnaire one week after treatment. It may be more feasible to administer a shorter more refined questionnaire at a longer interval after treatment. This pilot questionnaire was also limited in the complexity of the response options which currently include 3 options (yes, no, or I don't know). This could be improved by adding a 5 point response scale instead of 3. There were also questions that may could be further refined and specified, for example more questions on side effects could be helpful.

Ultimately the aim of the questionnaire should be to get helpful feedback about the service from as many service users as possible. Based on these suggestions we have designed a refined shorter questionnaire that may be more feasible to be used with this patient group (see appendix 4).

4.3 Feedback to Service

- A summary report was collated and presented to representatives for the CQC visit
- The data from this report will be presented to service managers at a Business meeting
- This report will be prepared as a publication to help disseminate knowledge and affirm the acceptability of ECT among professionals

- A brief report will be placed visibly and accessibly in the ECT service and the MHOA team service so that it is visible to service users and their families

4.4 Areas of future development

Ensuring that servicer users are receiving quality care and that they are satisfied with the experience is the top priority of any NHS service. Given the controversial stance towards ECT that many people and professionals still take, a well designed feedback questionnaire for the ECT service is an important area of research and development. It would be interesting further develop a range of feedback tools that could be used at different time points in service users' treatment and recovery. Perhaps initially service users may not feel well enough to engage in a long questionnaire or qualitative interview, but a short tailored questionnaire may be appropriate. When service users are well a longer more complex feedback survey could be used that could incorporate more qualitative questions to get a wider range of feedback.

Based on the questionnaire feedback, for example 40% of service users experiencing powerlessness, and 50% of service users requesting more advice prior to consent; it would seem that psychology could have a more prominent role in the ECT service. Fisher (2012) outlined how a psychologist could help improve the experience of service users in the ECT service. He suggested that psychologists could assist with the process of consent, for example, offering service users a place to express fears and anxieties prior to or after treatment. This may help limit stigma and feelings of powerlessness. Psychologists' could also assist with the assessment of capacity, for example, based on shared formulation psychologists could explore why service users have agreed to treatment and could advise when service users consent because they think that the treatment may harm them or kill them. Formulation could also help service users to understand their experience of ECT, for example in the context of previous health care and how they understand their mental illness.

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APPENDIX 1 Questionnaires

PRE TREATMENT QUESTIONNAIRE

Name:_____
Date:_____

Date of Birth:_____

Please read the following questions and CIRCLE the answer that you think is correct. This is not a test and your answers will not affect your treatment, they will be used to help improve the service. Please use the space at the end to make any comments or recommendations.

Thank you for your assistance.

Procedure		*Answers:*		
1.	During ECT, anaesthetic /other medications are used	Yes	No	Don't know
2.	How often is ECT given per week?	1-2 times a week	5-6 times a week	Don't know
3.	How many ECTs do most patients require in one course?	Usually 1-10	More than 20	Don't know
4.	Where is the current applied?	To the head	To the arms	Don't know
5.	Who can administer ECT?	Psychiatrists / doctors	Technicians	Don't know
6.	What is ECT?	Treatment using electricity	Treatment using medication only	Don't know
7.	Certain investigations are needed before ECT	Yes	No	Don't know
8.	How long is the current applied?	Seconds	More than 1 minute	Don't know
9.	How is ECT given?	By a special machine	By medication only	Don't know
Indications				

10.	ECT is often used to …	Treat acute psychiatric conditions	Treat physical illness	Don't know
11.	ECT is given to only those patients who have little chance of improvement	No	Yes	Don't know
12.	ECT can also be given to older persons (>60-65 yr)	Yes	No	Don't know
13.	ECT is given only to inpatients	No	Yes	Don't know
14.	Pregnant women can also receive ECT	Yes	No	Don't know
Effectiveness/mechanism of action				
15.	ECT is useful in treating psychiatric disorders	Yes	No	Don't know
16.	Compared to medications, how useful is ECT?	More or equally useful	Not useful	Don't know
17.	ECT often worsens the psychiatric illness	No	Yes	Don't know
18.	How does the ECT work?	By correcting brain-changes causing symptoms	By damaging the brain	Don't know
19.	The side effects of ECT last only for a short while	Yes	No	Don't know
20.	Scientific evidence favours the usefulness of ECT	Yes	No	Don't know
Side effects				
21.	Use of ECT leads to temporary impairment of memory	Yes	No	Don't know
22.	Use of ECT leads to permanent loss of memory	No	Yes	Don't know
23.	ECT results in permanent damage to brain	No	Yes	Don't know
24.	ECT can damage other body-parts permanently	No	Yes	Don't know
25.	During the ECT chances of death are very high	No	Yes	Don't know
26.	Headache is a common side effect of ECT	Yes	No	Don't know

27.	Most of patients receiving ECT develop epilepsy later	No	Yes	Don't know

Comments:

_____

_____

_____

POST TREATMENT QUESTIONNAIRE

Name:_____ Date:
_____

Date of birth:_____

Please read the following questions and circle the answer that best applies to you. Please use the space at the end to make any comments or recommendations. Please know that your answers will not affect your treatment and will be anonymous and confidential. We will use the information to help improve the ECT service.

Thank you for your assistance.

Post Treatment Questions:
Experience of ECT

1.	How helpful was ECT in your case?	Very helpful Undecided Not at all helpful
2.	Does your experience suggest that ECT is better than drugs?	Yes Undecided No
3.	Experience of night prior to the day of ECT	Not unpleasant Undecided Unpleasant
4.	Experience of waiting for your turn for ECT	Not unpleasant Undecided Unpleasant
5.	Experience of procedure of ECT	Not unpleasant Undecided Unpleasant
6.	Experience after waking up after receiving ECT	Not unpleasant Undecided

		Unpleasant
7.	Experience with any long term side effects	Not unpleasant Undecided Unpleasant
8.	How do you rate our overall experience with ECT?	Not unpleasant Undecided unpleasant
9.	How frightening or upsetting was ECT compared to what you expected?	Not at all frightening Very frightening slightly frightening
10.	How do you compare receiving ECT to visiting a dentist?	Less unpleasant Undecided More/ equally unpleasant
11.	Did ECT upset you so much that you would be reluctant to accept it again?	No Undecided Yes
12.	Considering the effect of ECT, was it delayed in your case?	Yes Undecided No
13.	How was your experience with the process of informed consent?	Not unpleasant Undecided Unpleasant
14.	Do you feel you received sufficient information regarding ECT prior to treatment?	Yes Undecided No
15.	Did you ever feel you were being forced into accepting ECT?	No Undecided Yes
16.	Why did you agree to have ECT?	Illness had lasted too long Illness was very severe Trusted doctor's advice

The process of consent

17.	**Who discussed consent with you?**	**Doctor/Psychiatrist** **Nurse** **Don't remember**
18.	Did you sign a form giving consent?	No Undecided Yes
19.	Were you in distress when giving consent?	No Undecided Yes
20.	Did you feel supported and listened to while giving consent?	No Undecided Yes
21.	Would you have preferred additional support and advice prior to giving	No Undecided Yes

	consent?	

Throughout the ECT procedure:

22.	**Did you experience feelings of powerlessness?**	**No** **Undecided** **Yes**
23.	Did you experience feelings of humiliation?	No Undecided Yes
24.	Did you experience feelings of lack of control?	No Undecided Yes

I experienced the following side effects directly after ECT:

1.	**Memory loss**	**Mild** **Severe** **Don't remember**
2.	Headache	Mild Severe Don't remember
3.	Confusion	Mild Severe Don't remember
4.	Clumsiness	Mild Severe Don't remember
5.	Nausea or vomiting	Mild Severe Don't remember
6.	Eyesight problems	Mild Severe Don't remember
7.	Other	Mild Severe Don't remember

Patients' Attitudes towards ECT

1.	I am glad that I received ECT	Agree	Don't know	Disagree
2.	I will advise a close relative to receive ECT if recommended	Agree	Don't know	Disagree
3.	Treatment with ECT is cruel	Agree	Don't know	Disagree
4.	ECT is an inhuman treatment	Agree	Don't know	Disagree
5.	ECT is dangerous and should not be used	Agree	Don't know	Disagree
6.	ECT is often given to people who do not need it	Agree	Don't know	Disagree
7.	ECT is given indiscriminately to people	Agree	Don't know	Disagree
8.	ECT is often given as a punishment to violent/angry patients	Agree	Don't know	Disagree
9.	ECT is the worst treatment option under any circumstance	Agree	Don't know	Disagree
10.	Treatment with ECT should be outlawed	Agree	Don't know	Disagree
11.	Treatment with ECT is outdated	Agree	Don't know	Disagree
12.	ECT gets you better quicker than medications	Agree	Don't know	Disagree
13.	ECT is at times life saving	Agree	Don't know	Disagree

14.	Following discovery of new medicines, treatment with ECT is never required	Agree	Don't know	Disagree
15.	Once a person is given ECT, in future whenever he becomes ill ECT is the only treatment option	Agree	Don't know	Disagree
16.	If ECT fails in a patient, then no other treatment will succeed	Agree	Don't know	Disagree

17.	**If recommended, I would receive ECT treatment again**	**No Undecided Yes**
18.	In the future I would prefer psychological therapy over ECT	No Undecided Yes

Comments:

_____

_____

_____

_____

_____

____

APPENDIX 2 Qualitative Feedback: Patient Quotations

1. 'I don't want to have no more ECT, I want to concentrate on depot injection.'
2. no comments
3. no comments
4. 'All my life I have experienced difficulty thinking. I believe the medication is of some benefit in curing this but ECT is far more effective. I have not been cured fully yet, but have come along way towards it. In the past I believed without understanding fully as my condition meant that I couldn't think lucidly, that a person had 2 souls, and a schizophrenic person was someone who had used this fact to trick society, by showing one of these souls to the world and hiding the other soul. What then happened was that they forgot, that they had done this and the two souls came into conflict with each other. Whether this is true or not I don't know, but ECT is a brilliantly effective treatment for whatever medical condition I have and perhaps if more people realized this then there would be less reliance on medication and a cure.'
5. no comments
6. 'Staff were very nice, I was a bit nervous beforehand. It was not a long wait. The 2nd time was more collaborative because I was more well. I was moved from one team to another team and it was difficult with aftercare the first time out of the hospital. Any information on long term side effects, memory and length of course? I experience side effects such as word finding difficulty. My grandfather had it and it worked, is there a genetic component? I do feel that it has worked for me. During the 1st course the paranoia went away straight away. More recently Ive had major depression and this second time it has gone more gradually. Now I feel much more like myself. Also wondering how long does the effect last (meaning recovery)?' (quotation from phone interview)
7. no comments
8. 'Feeling fine now'
9. 'Yes it was beneficial for me, got rid of my depression. I didn't feel isolated anymore, Im eating less and back on track. Hopeful now for the future, agreed to take medication even thought I thought it wouldn't help, but it is helping. Sometimes still not feeling that good because of the medication. After ECT I wanted to get back to work and get a job. (quotation from phone interview)
10. 'I have had ECT 3 times, twice as an inpatient. It has been successful (or partially successful) since'.

APPENDIX 3 Ethical Approval

South London and Maudsley NHS
NHS Foundation Trust

Project Proposal Form (PPF) for Clinical Audit, Service Evaluation and other Quality Improvement Projects

Should you require any assistance with completing this proforma, please contact your Local Clinical Audit Project Officer or, for Trustwide audits, the Clinical Audit & Effectiveness Team (details are available on the SLaM Clinical Audit & Effectiveness Internet Site). For local team-based or CAG-wide projects please send your completed PPF to your local Audit Project Manager/Officer, for ethical approval. For Trustwide projects please send your completed PPF to the Corporate Audit Dept. All relevant contact details are on the SLaM Clinical Audit & Effectiveness Team Intranet site.

1(a) Project lead details:	
Name: Drs Dene Robertson and Andrew Mogg	**Job title: Consultant Psychiatrists**
Work Address: Bethlem Hospital, Maudsley Hospital	
Telephone: 02032284897	**E-mail: dene.robertson@slam.nhs.uk; andrew.mogg@slam.nhs.uk**
Within CAG (please specify) MHOA CAG **Multiple-CAG (please specify)** The majority of patients receiving ECT are cared for exclusively by the MHOA CAG, though ECT is also delivered to patients from other CAGs by the MHOA CAG. This project evaluates the delivery of ECT, not other aspects of treatment, so this project is contained within the MHOA CAG. **Trustwide:** ☐	
1(b) Project Title: Patient Perspectives on the SLaM ECT service	
Project start date: 10/04/2014	**Project end date: 10/04/2015**

1(c) Please tick ✓ one box: Is this project a:		
Clinical Audit ☐ **(i.e. measures a standard)**	**Service Evaluation** ✓ ☐ **(e.g. patient survey)**	**Other Quality Improvement Project** ☐ **(please specify)** _____

2 (a) Overall project aim or purpose of the audit:

The aim of the current service evaluation project is to review participants' experiences of ECT treatment at the Bethlem and Maudsley ECT clinic. Specifically, patients' knowledge of the ECT process will be reviewed before and after ECT treatment. Patients will be asked to comment on their expectations and experience of treatment with the aim to inform and improve how knowledge of the ECT process is shared and disseminated to patients. Patients will also have the opportunity to comment openly on what they would improve about the service and what worked well. Patient outcomes will also be reviewed and correlated with reported experience of the service.

2(b) Specific objectives. What are the audit standards or criteria? The definition of a clinical audit is that it compares practice to agreed standards such as those defined in NICE guidelines and clinical policies, protocols and procedures. Please also state the source of your standards or criteria (for non-audit projects, clarify measures).

The primary standards/criteria relates to those relating to service user involvement, as in accordance with SLAM policy. These guidelines have been taken from the "South London and Maudsley NHS Trust. (SLaM): Patient and Public Involvement Policy, Guiding Principles and Resource Pack", specifically those relating to service users:

1. To increasingly involve and consult with service users regarding the service provision/ care they receive.

3. A policy to involve and consult with service users in the planning and provision of services within SLAM and in any proposed changes to services.

The project will allow service users to voice their individual experiences of the ECT service, so as to ensure quality and acceptability of the service.

For those deemed able to give consent NICE guidelines (2008) state: 'To help in the discussion, full and appropriate information about ECT should be given, including information about its potential risks and benefits, both general and specific to the individual.' This audit will assess patients access to information and understanding of the information provided that explains the ECT process and experience.

2 (c) In which ways do you think the project will improve patient care / outcomes?

Information acquired from the audit will be used to further develop the ECT service, for example improving patients' access to information about ECT and improving their experience during the treatment. Additionally a better understanding of the ECT process may lead to improved patient experience which in turn may improve shared knowledge, access and understanding of ECT as a therapeutic option.

3(a) Who will be on the audit steering group?

Jo Cresswell, ECT lead nurse, Dr Dene Robertson, Dr Andrew Mogg, Clare Killikelly. If possible a patient representative will be included.

3(b) What consideration has been given to the involvement of patients, carers or the public?

☐ Full user involvement at all stages of the audit

☐ ✓Partial user involvement (please state which stages)

This audit will work with patients as advisors across various different stages of the project development. Interviews will be with service users, whose account will shape overall themes. Outcomes and changes to service delivery will be fed back to participants if they wish to be kept informed.

☐ No user involvement (please state why not)

_____

3(c) Are you planning to collect data on any of the following equalities protected characteristics? (please tick all that apply)

Age ✓ ☐ Disability ☐ Ethnicity ☐
Gender re-assignment ☐

Pregnancy and maternity ☐ Religion or Belief ☐ Sex ✓ ☐ Sexual orientation ☐

3(d) Will you analyse your results or service outcomes to see if there is variation between equalities protected characteristics?

Yes ✓ ☐ No ☐

Comments: _____

4. Information Governance Requirements: When planning an audit, each project should be evaluated with regard to whether **Personal Identifiable Information (PII)** needs to be used. Unless there is genuine justification, all PII should be taken out to effectively anonymise the data for audit and research purposes. If you are unsure or need guidance and advice, please contact: dataprotectionoffice@slam.nhs.uk **Personal identifiable information (PII)** is any piece of information which can potentially be used to uniquely identify, contact, or locate an individual including name, address, full post code, date of birth, gender, ethnicity, NHS number, photographs, videos, audio-tapes etc.

4(a) Will the data be fully	☐ ✓ Yes	☐ No (patient identifiers) ☐ No (staff identifiers)

anonymised?	If yes, how: Questionnaires will be allocated a number which will be linked to participant initials in a password protected electronic data base. Data will therefore be kept anonymously, but can be removed should an individual wish to no longer participate. All names and service details will be anonymised and/or changed to protect the identity of the participant when qualitative data is reported.	If no, why not: _____ If no, which personal identifiers will be used: _____ If no, have you made arrangements to gain consent from data subjects? ☐ Yes ☐ No
4(b) Where will the data be recorded?	☐ ✓ Manual forms ☐ ✓ Electronic spreadsheet	☐ Electronic forms ☐ ✓ Electronic database ☐ Other (please specify)
4(c) Security arrangements	☐ ✓ Locked cabinet ☐✓ Locked office ☐ Other (please specify) _____	☐ On shared folder on SLaM network ☐ On secure network outside SLaM ☐ Files Password protected ☐ ✓ Login required
4(d) Will the data be transferred outside SLaM	☐ Yes, in an anonymised format ☐ Yes, with identifiers **You must contact dataprotectionoffice@slam.nhs.uk to register any transfer of personal identifiable information in advance.**	☐ Yes, outside the EU ☐ ✓ No

	If yes, how? Physically in person Physically using a secure courier Physically using registered mail services	Electronically using NHS.net e-mail (NHSmail) Electronically using file encryption and other email Electronically using encrypted portable media Other (please specify)

4(e) Information Asset Owner: (Individual responsible for the data)	Name: Clare Killikelly	CAG:
	Job title: Trainee Clinical Psychologist	Organisation: SLaM, IoP

Data Collection (please answer ALL of the following questions)	
5(a) Where from? e.g. clinical records/ePJS, INSIGHT/CRIS, other service records, direct from patients or clinicians, observations of practice, DATIX.	From service users and clinical records (ePJS) Patients who are deemed to have capacity to consent to ECT treatment will be approached for this audit. Capacity to consent to treatment is assessed by the referring psychiatrist. For a patient who would like to participate in the audit but did not consent to treatment, specific capacity to participate in the audit will be assessed separately by a team psychiatrist. Additionally a statement will be included on the questionnaire to clarify that participating or not participating in this study will not affect the patients' treatment in any way.

5(b) How? The data source will obviously influence the method used to collect data. e.g. survey, interview, focus groups, data collection proforma. Please include any other significant aspects of your methodology.	New referrals will be approached within 1 week prior to their first ECT session and asked to complete a short questionnaire to determine their understanding of the upcoming ECT treatment. Patients will also have the opportunity to ask questions or to make open comments about their experience so far. Within 1 week of completing ECT treatment patients will be asked to fill out a brief questionnaire about their experience of the service and will have the opportunity to comment openly about the negative and positive aspects of their experience with the service.
5(c) How much? As a rough guide, a sample should include 20-50 cases.	A total of 20 patients (minimum) will be asked to participate. Participants will be those referred to the ECT department and in receipt of ECT for any reason.
5(d) Pilot Audit? Yes	A brief pilot audit will be undertaken; patients will be asked to comment on the development of the questionnaires
6(a) With whom and where will the final report be shared? e.g. which committees or service meetings The final report for this service evaluation will be shared with service users and the ECT teams. The main results and overall themes will be disseminated via academic publication. _____	
6(b) Who will take responsibility for disseminating the results of the project and following through recommendations and actions? And how and when will the recommendations and actions be evaluated, monitored and reviewed? _____C.Killikelly and the ECT team_____	
All completed projects must be followed up with a completed action plan form, available on the SLaM Clinical Audit & Effectiveness Intranet site http://sites.intranet.slam.nhs.uk/cg/default.aspx (Audit Report Template Appendix B)	

7) Project Approval	
7(a) Information Governance Approval: IG Audit approval given by: _____ Date Audit IG approved:_____	**7(b) Project Ethical approval given by:** Clinical Audit Ethical approval given by: _____ Date of Committee Approval:_____ ☐ Quality Governance Committee ☐ Drugs and Therapeutics Committee ☐ CAG Clinical Governance/Audit Committee

APPENDIX 4 Draft Short Questionnaire

Recommended questions for shorter version of questionnaire with 26 questions and where possible 5 response options for each question (including strongly agree, agree, disagree, strongly disagree and don't know)

Knowledge

1. Certain investigations are needed before ECT	**Yes**	**No**	**Don't know**
2. How long is the current applied?	To the head	To the arms	Don't know
3. How is ECT given?	By a special machine	By medication only	Don't know
4. ECT is often used to …	Treat acute psychiatric conditions	Treat physical illness	Don't know
5. How many ECTs do most service users require in one course?	Usually 1-10	More than 20	Don't know

Side Effects

6. Use of ECT leads to temporary impairment of memory	**Strongly agree, agree, disagree, strongly disagree and don't know**
7. Use of ECT leads to permanent loss of memory	Strongly agree, agree, disagree, strongly disagree and don't know
8. ECT results in permanent damage to brain	Strongly agree, agree, disagree, strongly disagree and don't know
9. ECT can damage other body-parts permanently	Strongly agree, agree, disagree, strongly disagree and don't know
10. During the ECT chances of death are very high	Strongly agree, agree, disagree, strongly disagree and don't know
11. Headache is a common side effect of ECT	Strongly agree, agree, disagree, strongly disagree and don't know
12. Most of service users receiving ECT	Strongly agree, agree, disagree,

develop epilepsy later	strongly disagree and don't know

Experience of ECT Procedure

13. How helpful was ECT in your case?	**Strongly agree, agree, disagree, strongly disagree and don't know**
14. Does your experience suggest that ECT is better than drugs?	Strongly agree, agree, disagree, strongly disagree and don't know
15. Did ECT upset you so much that you would be reluctant to accept it again?	Strongly agree, agree, disagree, strongly disagree and don't know
16. How frightening or upsetting was ECT compared to what you expected?	Strongly agree, agree, disagree, strongly disagree and don't know
17. Experience after waking up after receiving ECT	Strongly agree, agree, disagree, strongly disagree and don't know
18. Experience with any long term side effects	Strongly agree, agree, disagree, strongly disagree and don't know
19. How do you rate our overall experience with ECT?	Strongly agree, agree, disagree, strongly disagree and don't know
20. Do you feel you received sufficient information regarding ECT prior to treatment?	Strongly agree, agree, disagree, strongly disagree and don't know
21. Did you ever feel you were being forced into accepting ECT?	Strongly agree, agree, disagree, strongly disagree and don't know
22. How likely are you to recommend our service to friends and family if they needed similar care or treatment?	Strongly agree, agree, disagree, strongly disagree and don't know

Psychological Factors

23. Did you experience feelings of powerlessness?	**Strongly agree, agree, disagree, strongly disagree and don't know**
24. Did you feel involved in making	Strongly agree, agree, disagree, strongly

decisions about your care?	disagree and don't know
25. Did you experience feelings of lack of control?	Strongly agree, agree, disagree, strongly disagree and don't know
26. Would you have preferred additional support and advice prior to giving consent?	Strongly agree, agree, disagree, strongly disagree and don't know