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Service Engagement and Disengagement in First Episode Psychosis

Kirsty McPhilemy
B.A (Hons) MSc

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Institute of Health and Wellbeing
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Foreword

Primary data collection for the original research project 'Exploring the Experiences of People with Psychosis and Type 2 Diabetes (EXPAND)' was adversely affected by the COVID-19 pandemic. This subsequently led to the researcher abandoning their original project due to suspension in recruitment set out by NHS Research & Development. The following systematic review and secondary data study therefore represents a new research topic. Some of the accompanying appendices refer to the original research topic and are titled accordingly.

Chapter 1 Systematic Review

First episode psychosis and disengagement from early intervention services: An updated systematic review

Chapter word count: 6,589 (including tables, figures, references)

Prepared in accordance with Early Intervention in Psychiatry (see appendix 1:1

Abstract

Aim

This review offers an up to date examination of rates and predictors of engagement and disengagement amongst individuals with first episode psychosis using specialist early intervention services.

Methods

Three databases (Medline, PSYCHINFO and CINAHL) were systematically searched. Studies that examined engagement or disengagement from early intervention services for first episode psychosis, and published from 2012 and onwards, were included in the study. Nine papers were identified. The CASP Cohort Study Checklist was used to critically appraise methodological quality of included papers.

Results

Disengagement rates varied from 11.7% to 56.3% (*Mdn=13%).* Only two papers used validated tools to measure engagement. Poor medication compliance and substance abuse emerged as more robust predictors of disengagement. Inconsistent findings were found for clinical variables. Methodological differences across studies made comparisons between studies difficult.

Conclusions

In this up-to-date review of definitions and predictors of engagement in first episode psychosis, there still lacks consensus regarding a goal standard definition and measurement of engagement. There is a need for clearly defined measurement of service engagement and disengagement.

Keywords

Early intervention, engagement, disengagement, systematic review, First episode psychosis

Word Count: 181

Introduction

First episode psychosis (FEP) can be a particularly distressing experience for individuals and those close to them. The onset of psychosis typically occurs during late adolescence and young adulthood during a time when individuals are transitioning into adult independence and embarking on new social and vocational opportunities. Experiences of psychosis are unique to the individual but can include experiences such as hallucinations, delusional beliefs, cognitive and interpersonal difficulties and changes in mood. Psychosis can result from a complex interaction of biological, psychological and the social aspects of human experience with much recent research highlighting the role of stressful life events and trauma (BPS, 2015). In particular, adverse childhood experiences greatly increases the likelihood of later expression of psychosis (Lataster et al., 2012). Rates of psychosis are also significantly higher in people from black and minority ethnic (BAME) backgrounds in the UK (Fearon et al., 2006) and their experiences of services can be poor (Boydell et al., 2012). The experience of overt and institutional racism can increase the rates of a host of mental health problems, including psychosis, and complex patterns of discrimination can make it less likely for BAME populations to seek help (Nicholls et al., 2007). Early intervention (EI) services for FEP were developed from the evidence that early intervention can have significant impact on the course of illness (Birchwood et al., 1998). EI services typically offer intensive case management delivered by a multidisciplinary team with a strong focus on developing therapeutic alliance to increase the likelihood of service engagement. The main goals of EI services are often to achieve symptom reduction, social recovery and relapse prevention.

The effectiveness of any clinical intervention is dependent on the patient's willingness to engage meaningfully with treatment. Disengagement in mental health services is an ongoing challenge, with reported rates of up to 50% higher than that of any other medical services (Mitchell et al., 2007). Definitions of disengagement can vary from refusal to

participate in a mental health intervention, to attending appointments but not taking part in session content (Tindall et al., 2018). Heterogeneity of definitions across studies can make comparisons difficult. Despite these methodological challenges, young adults experiencing first episode psychosis (FEP) have been identified as being a particularly challenging population group to engage (Dixon et al., 2016) with reported delays in accessing treatment of 1-3 years, and high attrition rates of up to 80% within the first year of entry to general mental health services (Kane et al., 2012). Early drop out from such services is associated with slower recovery, increased need for hospitalisation, higher levels of functional impairment (Dixon et al., 2016) and increased relapse (Stowkowy et el., 2012). Disengagement in this population group is therefore of particular concern.

Engagement is a multi-faceted phenomenon and can change in response to various factors including stage of treatment, patients' attitudes towards recovery, and changes in life and social circumstances (Lal & Malla, 2015). Specialised early intervention services for FEP have a specific emphasis on service engagement and multidisciplinary working to provide intensive biopsychosocial interventions to help reduce the duration of untreated psychosis, improve psychiatric symptoms and psychological outcomes, promote social and vocational recovery and prevention of relapse (Birchwood, 2014). Such services are more successful in engaging young people in care and for longer compared to that of typical mental health services (Dixon et al., 2015; Kane et al., 2016). A vital part of the success of these services is the role of the therapeutic alliance (Kvgric et al., 2013; Melau et al., 2015) which has consistently be shown to be a reliable predictor of successful outcomes in therapy (Hovarth et al., 2011; Tindal et al., 2020) and found to be a prerequisite for service engagement and good psychiatric outcomes in the FEP population (Melau et al., 2015). However, meta-analyses of therapeutic alliance on outcomes in therapy report effect sizes of r=0.27 suggesting that although clearly an important and necessary factor to promote recovery outcomes, not a sufficient in itself (Del Re et al., 2012).

An understanding of the factors associated with engagement, including demographic and clinical predictors, is crucial improving engagement and in developing approaches to reduce the risk of disengagement. A systematic review published by Doyle and colleagues (2012) reported that disengagement rates in early intervention services for FEP varied from 20.5% to 40% across ten studies with the most robust predictors for disengagement shown to be co-morbid substance abuse and lack of family support. Doyle and colleagues (2014) found a lack of reporting on the potential impact of ethnicity, culture and deprivation on disengagement. However, such factors are commonly associated with disengagement in the broader mental health literature (Lal & Malla, 2015). There was also found to be no accepted definition or measurement of engagement or disengagement across the studies. This was mirrored by a recent review by Reynolds and colleagues (2019) which looked at how disengagement in FEP from mental health services were defined, measured and operationalised across 30 published studies and found that very few studies considered similar factors in their definition.

The purpose of this review is to build upon the previous review by Doyle and colleagues (2014) and to examine the current rates of disengagement, and predictors of engagement and disengagement amongst individuals living with FEP using EI services. The aims of the current review are as follows:

1. To provide an up to date account of the rates of disengagement in early intervention services
2. To examine definitions of engagement and disengagement
3. To identify predictors of engagement and disengagement.

Methods

Eligibility Criteria

Participants

Individuals with a first episode psychosis.

Intervention/ Exposure

Specialist early intervention service for first episode psychosis.

Comparator / Context

Studies were limited to early intervention services for first episode psychosis. Studies that were set in general mental health studies were excluded from the review.

Outcome

Rates and predictors of engagement and disengagement in EI services.

Study Design

Studies included cohort studies and those which were published from 2012 and onwards. Studies were excluded if they were not published in English, dissertations, conference abstracts, and book chapters. Qualitative research and studies which employed mixed methods were excluded from the review

Search Strategy

The databases Medline (2012-2020), PsychInfo (2012-2020) and CINAHL (2012-2020) were searched on the 18th May 2020 using the following search string: (schizophrenia or psychosis or psychoses or psychotic disorder or schizophrenic disorder or schizoaffective disorder) OR (first episode psychosis or early psychosis or early onset psychosis) AND (engagement or involvement or participation) or (disengagement or non-compliance) or (dropout or drop out or drop-out) AND (engagement predictors) OR (predict or predictors or predictive). The review looked to update results from a systematic review by Doyle and colleagues (2014) which searched papers published up to 2012. The current review therefore

searched for papers published from 2012 onwards. Title and abstract screenings were conducted on the search to decide upon which papers to exclude based on inclusion criteria. Papers which met criteria were then reviewed in full and independently assessed on its relevance to decide whether to include in the review. A manual search of the literature was also conducted in order to exhaust all possibilities and reduce bias. This included searching reference lists of included articles to identify any pertinent studies. Citation searching of included studies was then carried out and lastly, a manual search on Google scholar was conducted using key terms and searching prominent researchers in the field of first episode psychosis.

Ratings of Methodological Quality

The Critical Appraisal Skills Programme (CASP) quality tool for cohort studies was used to assess the quality of the studies included in the review (CASP, 2018). The tool consists of 12 questions to assess components such as the purpose of the study, recruitment, risk of bias, accountability of cofounding factors, follow-up, levels of evidence, comparability and implications for practice. The tool does not act as a checklist or offer a scoring system but helps reviewers focus on key concepts for evaluating the validity of studies and was used in the current review to encourage critical consideration of studies and the area of engagement. Data were extracted from eligible full-texts and structured in an extraction excel sheet which classified patient characteristics, outcomes, and critical appraisal of the papers using the CASP.

Results

The search strategy yielded 328 articles following deduplication. Following screening of titles and abstracts, the final sample consisted of 9 articles that met eligibility criteria for inclusion in the review. Figure 1 shows a diagram of the searching process.

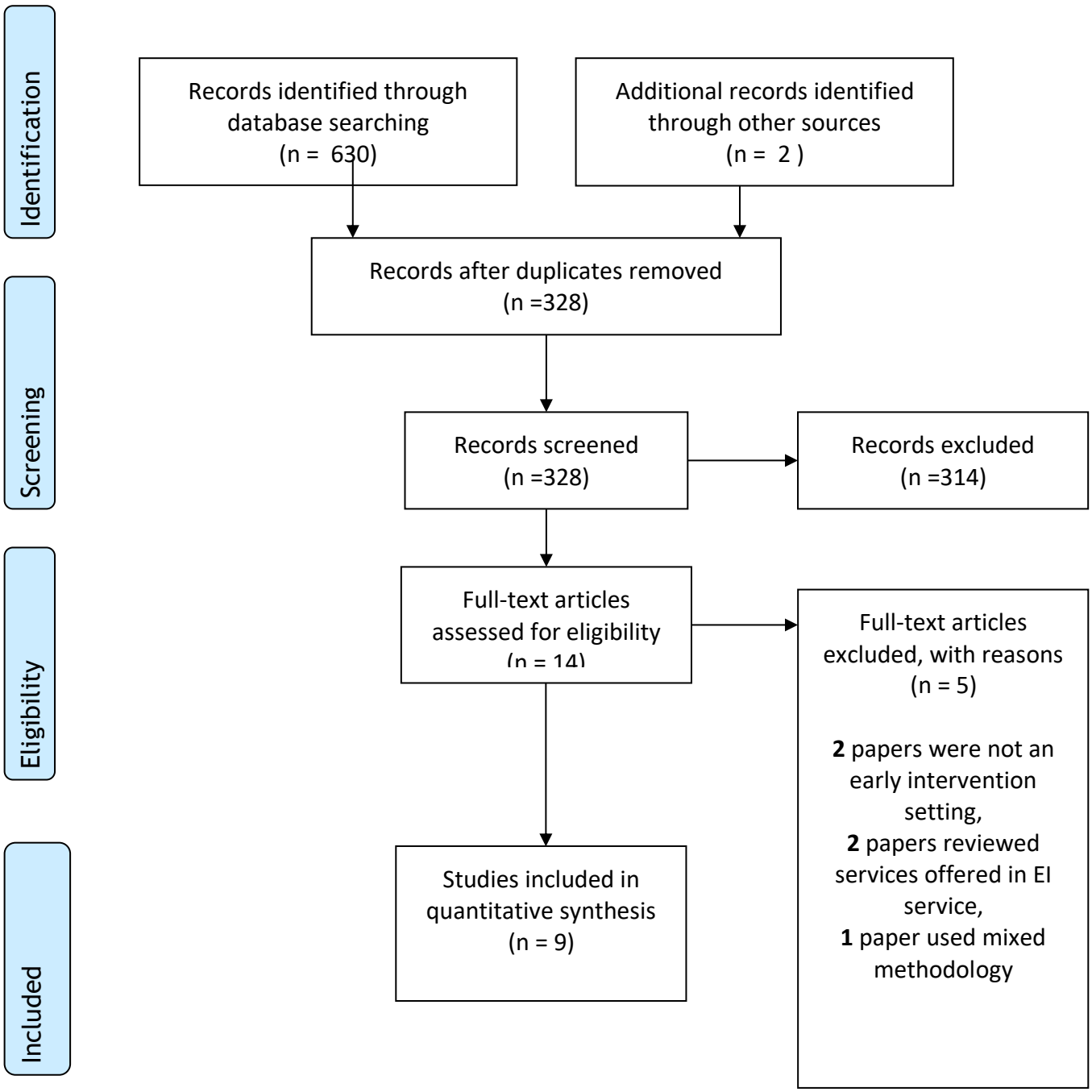
Identification
Screening
Eligibility
Included
Records identified through database searching (n = 630)
Additional records identified through other sources (n = 2)
Records after duplicates removed (n =328)
Records screened (n =328)
Records excluded (n =314)
Full-text articles assessed for eligibility (n = 14)
Full-text articles excluded, with reasons (n = 5)
2 papers were not an early intervention setting,
2 papers reviewed services offered in EI service,
1 paper used mixed methodology
Studies included in quantitative synthesis (n = 9)

Figure 1: *Flowchart of the study selection process and results for inclusion in the systematic review.*

Study Characteristics

The combined sample was comprised of 3925 participants. Samples ranged from *n*=64 (MacBeth et al., 2013) to *n*=786 (Solmi et al., 2018). Males made up 61.4% (*n*= 2410) of the sample. Publication dates were between 2013 (MacBeth et al., 2013; Zheng et al., 2013) to 2019 (Kim et al., 2019; Lavelic et al., 2019). Three studies were based in the UK, 2 based in Canada, 2 in Hong Kong, 1 in Singapore and 1 in Australia. In terms of methodology, five studies were prospective (Casey et al., 2016; Maraj et al., 2018; Ouelett-Plamondon et al., 2015; Solmi et al., 2018; Zheng et al., 2013) three retrospective (Chan et al., 2014; Kim et al., 2019; Lau et al., 2017) and 1 cross-sectional (MacBeth et al., 2013). Study characteristics and main findings from studies can be found in table 1.

Rates of Disengagement

Seven studies reported rates of disengagement which ranged from 11.7% to 56.3% (*Mdn* = 13%). The majority of studies reported rates of disengagement within the context of a two-year follow up period, with the exception of Solmi et al., (2018) who reported rates of disengagement over a three-year period of care.

Kim et al. (2019) reported the highest rates of disengagement with over half of an Australian cohort disengaging at least once over the course of treatment (56.3%). However, they found that the majority of individuals re-engaged (85.5%) with only a small percentage of participants never re-engaging after initial drop out. Solmi et al., (2018) reported the lowest rates of disengagement (11.7%) in a cohort in the East of England. These varying rates of disengagement should however be viewed in light of the wide variety of definitions used to capture disengagement.

Author & Year	Setting	N	Mean Age	Male N(%)	Ethnicity	Study Design	Measurement / Definition of disengagement	Relevant Findings
Casey et al. 2016	Early Intervention Service Birmingham, UK	103	23	73 (71%)	Asian 33% Black 25% White 36% Other 8%	Prospective study over a 2 year period	Results of SOLES questionnaire. Higher score represent better engagement.	Predictors of engagement Beliefs that mental illness is caused by social stress (p=0.002) or thinking odd thoughts (p=0.008). Individuals with no qualifications have higher engagement scores that those educated at a higher level (p=0.0015). Duration of untreated illness (DUI) significantly predicted higher engagement scores, but only for values > 1220 days
Chan et al. 2014	Early Assessment Service for Young People with Psychosis Hong Kong	700	20.65	360 (51%)	Not reported	Retrospective historical case control design with two year follow-up	Continuous default of out-patient appointments despite therapeutic need and active tracing from staff. No standardised tool of measurement used.	Rate of disengagement 13% within 2-year period Significant predictors of disengagement Fewer baseline negative symptoms (p=0.002), diagnosis other than schizophrenia spectrum disorder (p>0.001) and poor medication compliance in first three months (p<0.001).
Kim et al. 2019	Early Psychosis Prevention and Intervention Centre (EPPIC) Melbourne, Australia	700	19.5	421 (60.10)	Not reported	Retrospective case design 2 years follow up Naturalistic cohort study	Active refusal of any contact with the treatment facility or non-traceable.	Engagement Rates 56.3% disengaged at least once during treatment period; however, the majority (85.5%) subsequently re-engaged. Significant Predictors of disengagement NEET (p=<0.001), family history of psychosis in the 2nd degree (p=0.03), cannabis abuse (p=0.001) No significant predictors of re-engagement emerged.
Lau et al. 2017	Early Assessment Service for Young People with Psychosis (EASY) Hong Kong	277	Mean age not reported N = 122 aged 15-25 years; N = 155 aged 26-64 years	126 (45)	Not reported	Retrospective with 2 year follow-up	Type I disengagement: defined as continuous default from the service. Type II: continuous default from service and re-engagement through hospitalisations. Type III: 2 or more consecutive defaults from the outpatient appointments and re-engaged to the service.	Rates of disengagement Type 1 = 13%, type II=4.3%, type III = 13.4% Predictors or disengagement Poor drug compliance predicted type I (p<0.01) type II (p>0.01) and type III disengagement (p=0.01). History of substance abuse (p=0.03) and history of self harm/suicide (p=0.03) also predicted type III disengagement. Younger people had significant earlier disengagement (p=0.025). Younger people (aged 15-25) had significant earlier disengagement (x^2=5.01, p=0.025) compared to those who were older (26-64).
MacBeth et al. 2013	Early Intervention services for psychosis Scotland	64	23.67	43(67%)	White British 90.6% Other 6.4% Not reported 3.1%	Cross-sectional study	Results of SES questionnaire. Lower scores indicate higher levels of engagement.	Engagement and clinical Correlates Poor clinical engagement is associated with greater positive (r=0.388), negative (r=0.653) and greater general (r^s=0.335) psychopathology and poorer premorbid social adjustment (r=0.426). Predictors of engagement Severity of negative symptoms significantly predicted engagement (p<0.001).

Maraj et al. 2018	Early Intervention for Psychosis Service Canada	297	22.8	203 (68.40)	Caucasian 66% Black 12% Asian 8% Other 14%	Prospective cohort study with 2-year follow-up	No clinical contact for at least three consecutive months.	Rate of disengagement 24.2% with an average time of disengagement of 13.3 (SD=5.7) months. Predictors of disengagement Rates were similar between immigrants and non-immigrants but reasons for disengagement differed. Medication non-adherence predicted disengagement ($p<0.05$) in all groups. For first generation immigrants age was an additional predictor. For second generation immigrants, material deprivation was an additional predictor.
Ouellet-Plamondon et al. 2015	Early Intervention service for first episode psychosis Montreal, Canada	223	22.97 Range 18-30	274 (81.5)	Country of origin Canada 58% USA 2% Europe 21% Africa 10% Carribean 24% Mexico, Central and South America 14% Middle Eastern and North Africa 15% Asia 8%	Longitudinal prospective cohort study with 2 year follow up	Participant refusal of follow-up or unreachable for more than three months	Rates of disengagement 6-18% Immigrants had three times the odds of attrition than non-immigrants for first generation ($p=0.49$) and second generation ($p=0.039$) immigrants.
Solmi et al. 2018	Early Intervention Service for First Episode Psychosis East Anglia, UK	786	Mean not reported. Range= 16-35	515 (65.78)	White British 77% White Other 12% Black 4% Other Black and Minority Ethnic 6% Bangledeshi/Pakistani 3%	Prospective study over three years	Disengagement assumed to occur when all possible ways to engage were explored by clinical team. Time period disengagement said to occur was usually 6-8 attempts over a 2-3 month period.	Rates of disengagement 11.7% over three-year period Predictors of disengagement Participants who did not received FEP diagnosis, had. DUI of between 5 and 8 weeks, history of polysubstance misuse had a great risk of disengagement Those who were unemployed, more severe psychomotor poverty, and first-rank delusions were at lower risk of disengagement
Zheng et al. 2013	Early Psychosis Intervention Programme (EPIP) Singapore	775	Mean age not reported. Range 15-40	395 (51)	Chinese 77% Malay 14% Indian 7% Other 2%	Prospective study Two years follow-up	A semi structured scale measuring the amount and type of contact maintained between case managers and patients. Disengagement said to occur when patients drop out without clinical resolution, or moves out of catchment area or refuses services.	Rates of disengagement 14% over two years follow-up Predictors of disengagement Malay ethnicity ($p<0.017$) and lower level of education ($p<0.009$).

Measurement of Service Engagement

Two studies investigated engagement using validated tools of measurement. MacBeth et al. (2013) used the Service Engagement Scale (SES; Tait et al., 2002) in which lower scores indicate better engagement, and Casey et al. (2016) used the Singh-O'Brien Level of Engagement Scales (SOLES; O'Brien et al., 2009) with higher scores indicating better engagement.

Seven studies investigated disengagement (Chan et al., 2014; Kim et al., 2019; Lau et al., 2017; Maraj et al., 2018; Ouellet-Plamondon et al., 2015; Solmi et al., 2018 and Zheng et al., 2013). Of these studies, one developed their own semi-structured scale to measure the amount and type of contact maintained between case managers and patients. There was no agreed upon definition of disengagement. Definitions ranged from dropping out of treatment before completion of EI programme (Zheng et al., 2013) to having no clinical contact for three months (Maraj et al., 2018). Lau et al. (2017) defined three types of disengagement which included continuous default from the service, continuous default and re-engagement through hospitalisation, and continuous defaults from out-patients and subsequent re-engagement. One study (Zheng et al., 2013) identified those who had moved out of the area as 'disengaged' whereas other studies explicitly stated this was not considered as disengagement (Solmi et al., 2018; Maraj et al., 2018).

For studies that focussed on disengagement, there did not seem to be an agreed time frame in which disengagement was said to occur. Three studies reported disengagement occurred when no clinical contact was made within three months (Ouellet-Plamondon et al., 2015; Maraj et al., 2018; Solmi et al., 2018) whilst others did not provide timeframes (Zheng et al., 2013).

Two studies reported on re-engagement of individuals who initially disengaged (Kim et al., 2019; Lau et al., 2017). In contrast, Zheng et al. (2013) considered those who

returned to treatment after dropping out as remaining in treatment. Therefore, those classified as disengaged in some studies, are classified as engaged in other studies.

Predictors of Disengagement

A summary of the findings related to predictors of engagement and disengagement can be found on table 2.

Sociodemographic predictors

All studies investigated sociodemographic predictors of engagement or disengagement and in general were consistent in their lack of findings. From the seven studies that explored gender, one study found weak evidence suggesting men to be at higher risk of disengagement (Solmi et al., 2018).

Lau et al. (2017) was the only study to find age as a significant variable and found that younger people aged 15 to 25 had significantly earlier disengagement compared to patients aged 26 to 64 years old. However, it should be noted that this sample was older than other samples in the review due to broader aged related entry criteria of the EI service under investigation.

Three studies explored the role of ethnicity. Two studies conducted in the UK (Solmi et al., 2019; Casey et al., 2016) did not find ethnicity to have a significant impact on level of engagement. In contrast, Zheng and colleagues (2013) found that Malay ethnicity, which represented 14% of the sample, was a significant predictor of disengagement amongst a cohort in Singapore.

Two Canadian studies explored immigrant status on levels of engagement with mixed results. Ouellet-Plamondon et al. (2015) found that immigrants were three times more likely to disengage from treatment. In contrast, Maraj et al. (2018) found that immigration status was not predictive of disengagement; however, reasons for disengagement differed between immigrant and non-immigrant groups with medication adherence being predictive

in both groups, and the addition of age and material deprivation being predictive in first- and second-generation immigrants, respectively. This may suggest consideration of different approaches when formulating engagement amongst immigrant populations in FEP.

Three studies explored employment, education and training and mixed findings were found. Whilst Kim et al. (2019) found not being in employment, education or training was a significant predictor of disengagement. Zheng et al. (2013) found no association. Additionally, Solmi et al. (2018) found that those in employment at baseline were at higher risk of disengaging.

Five studies investigated the impact of education on levels of engagement. Casey et al. (2016) found that individuals with no qualifications were found to have higher engagement scores than those educated to a higher level. Three studies found education was not predictive of disengagement (Chan et al., 2014; Lau et al., 2017; Maraj et al., 2018) whilst one study found individuals with less than six years of education were more likely to disengage (Zheng et al., 2013).

The previous systematic review found lack of family involvement to be a robust predicator of disengagement (Doyle et al., 2014). Studies included in the current review were consistent in their lack of findings between lack of family involvement and disengagement. Two studies explored lack of family involvement (Maraj et al., 2018; Solmi et al., 2018) and found no associations with disengagement. Two studies investigated family contact on rates of disengagement and found no significant results (Maraj et al., 2018; Solmi et al., 2018). Additionally, two other studies found living alone was not predictive of disengement (Lau et al., 2017; Zheng et al., 2013).

Clinical Predictors

Six studies investigated the role of clinical predictors with two studies looking at predictors of engagement (Casey et al. 2016; MacBeth et al., 2013) and four investigating their role in disengagement (Chan et al., 2014; Lau et al., 2017; Solmi et al., 2018; Zheng et al., 2013). Results of these studies were mixed. There was some evidence that lower symptom severity was associated with greater disengagement. Two studies (Solmi et al., 2018; Chan et al., 2014) found that patients who had fewer negative symptoms at baseline were more likely to disengage. In contrast, Macbeth et al. (2013) found severity of negative symptoms was predictive of poorer engagement. Other studies found no significant impact of negative symptoms on disengagement (Lau et al., 2017; Zheng et al., 2013). Severity of positive symptoms were not found to be predictive of disengagement (Chan et al., 2015; Lau et al., 2017) or engagement (MacBeth et al., 2013). People with more severe hallucinations were found to be at a higher risk of disengagement in one study (Solmi et al., 2018)

Substance Use

Five studies investigated the role of substance abuse on disengagement. Polysubstance abuse (Solmi et al., 2018), history of substance abuse (Lau et al., 2017) and cannabis use (Kim et al., 2019) were found to be significant predictors of disengagement. Chan et al., (2014) reported substance abuse history within the first six months of contact with EI service predicted disengagement in a cohort in Hong Kong but such results should be interpreted with caution due to low rates of substance abuse in their cohort compared to Western countries. Maraj et al. (2018) found no association between substance use and disengagement.

Diagnosis

Five studies included in the review investigated the role of diagnosis (Casey et al., 2016; Chan et al., 2014, Lau et al., 2017; Kim et al., 2019, Solmi et al., 2018). Two studies found diagnosis was predictive of disengagement (Chan et al., 2014; Solmi et al., 2018). A diagnosis other than schizophrenia spectrum disorder including; affective disorders with psychotic features, acute and transient psychosis, and unspecified non-organic psychosis, were associated with a two-fold increased risk of disengagement (Chan et al., 2014). There was also evidence that individuals using an EI service who were later found to not meet diagnostic criteria for FEP were significantly more likely to disengage.

Table 1 Studies that reported predictors of engagement or disengagement

		Casey et al (2018)*	Chan et al 2014**	Kim et al (2019) **	Lau et al., (2017)**	MacBeth et al., (2013)*	Maraj et al., 2018) **	Ouellet-Plamondon (2015)**	Solmi et al., 2018**	Zheng et al., 2013**
Sociodemographic										
	Age or age of onset	N	N	N	Y		N		N	N
	Gender	N	N	N	N	N	N		Y	
	Race / Ethnicity	N							N	Y
	Immigrant Status						N	Y		
	First Language									
	Living Status	N								
	Living alone or without family				N					N
	Family Contact						N		N	
	Marital Status	N			N					N
	Employment								Y**	
	Unemployed/not in education/not in training			Y						N
	Educational level	Y	N		N		N			Y
	Social Deprivation Index						N			
	Material Deprivation Index						N			
	SES	N								
Clinical										
	DUP	N								Y
	DUI	Y							Y**	
	Length of prodrome	N								
	CGI-SCH Positive		N		N					
	CGI-SCH negative		Y		N					
	Psychomotor povery								Y*	
	First-rank delusions								Y*	
	Greater Hallucinations symptoms								Y**	
	Prodrome	N								
	SOFAS		N							
	PANSS total score									
	PANSS negative					Y				N
	PANSS positive					N				
	PANSS general psychopathology					N				N
	PANSS insight									N
	Severity of manic symptoms								Y*	
Medication										
	Poor medication compliance		Y		Y		Y			
	Taking SGAs		N							
	Not Taking SGAs									
	History of substance abuse									
Premorbid										
	Forensic history				N					
	Family history of psychosis								N	

	1st degree relative				N							
	2nd degree relative				Y							
	Academic premorbid adjustment								N			
	Social premorbid adjustment								N			
	History of self harm or suicide attempt						Y					
Substance Use												
	Any substance abuse			N			Y			N		Y**
	Cannabis abuse				Y							
	Amphetamine use				N							
Psychological												
	Symptom attributions	N										
	Beliefs about mental illness	Y										
Diagnosis	Schizophrenia spectrum			N			N					
	Affective Psychosis				N							
	Non-Affective Psychosis				N							
	Substand Induced Psychosis											
	Diagnosis other than schizo-affective			Y								
	Other psychosis						N					
	No FEP											Y**
	Diagnostic groups	N										

*denotes predictors of engagement **denotes predictors of disengagement

SES: socio-economic status; DUP: duration of untreated psychosis; DUI: duration of untreated illness; CGI SCH: Clinical Global Impression – Schizophrenia scale; SOFAS: the Social and Occupational Functioning Scale; PANSS: the Positive and Negative Symptom Scale; QOL: Quality of Life; GAF:Global Assessment of Functioning; FEP: first episode psychosis

Quality of Studies

Critical appraisal showed that sampling bias was prominent across studies. In general, females were under-represented across studies accounting for 38.6% of the overall sample. Casey et al. (2016) and Ouellet-Plamondon et al. (2015) had a particularly high percentage of males in their sample, 71% and 81.5% respectively. Zheng et al. (2013) had particularly high sampling bias by excluding those who had a history of substance abuse and forensic history despite these being evidenced as robust predictor of disengagement (Doyle et al., 2014). They also included those who had moved out of the area in their definition of disengagement, a factor which most other studies explicitly stated was not included in their definition of disengagement (Solmi et al., 2018; Maraj et al., 2018).

Heterogeneity in definitions and measurement of engagement is also a cause of concern with only two studies using validated measures of engagement (Casey et al., 2016; MacBeth et al., 2013). A lack of consensus regarding the definition of engagement and disengagement means the definition used in individual studies are unlikely to reflect all relevant aspects of the phenomena. Is it important to consider definition and criteria used for disengagement in individual studies before considering results in the context of local populations.

Studies with employed historical case control methodology (Chan et al., 2014; Kim et al., 2019; Lau et al., 2017) were prone to classification bias with methodological constraints meaning predictor variables under investigation were restricted to information available in clinical records. Additionally, confounders were a concern in some retrospective studies which were unable to assess for the contribution of previously evidenced variables on disengagement, such as lack of family involvement. Some studies were clear in which actions were taken to try and reduce classification bias (Chan et al., 2014; Kim et al., 2019) whilst others were not (Outlett-Plamondon et al., 2015). To control for bias in the collection of routine date, Chan et al., (2014) held weekly consensus meetings to ensure data and

reported ICC scores between clinicians and researchers which demonstrated satisfactory validity and reliability and other studies used advanced statistical methods to help control for the potential effects of confounders (Casey et al., 2016; Kim et al; 2019).

Longitudinal designs (Casey et al., 2016; Maraj et al., 2018; Ouellet-Plamondon et al., 2015; Zheng et al., 2013 Solmi et al., 2018) benefited from follow-up period spanning the length of the EI programme which varied from 24 to 36-month follow-up. MacBeth et al., (2013) was the only study in the review which used cross-sectional methodology, and had a smaller sample size (n=64) with subsequent limited statistical analyses and thus results from this study should be interpreted with some caution.

Discussion

This review offers an up to date review of engagement of individuals with FEP using an EI services. Similar to findings of a past systematic review (Doyle et al., 2014) no progress has been made with respect to developing consensus on the definition and measurement of engagement or disengagement. Current methods tend to use measures such as treatment adherence, therapeutic alliance and attendance; however, there are clear inconsistencies in how these are defined. Validated tools such as the SES (Tait et al., 2002) and SOLES (O'Brien et al., 2009) can be useful; however, these are clinician rated and there are a lack of measures that explicitly rate service users' perspectives on engagement or the quality of engagement. Lal & Malla (2015) have commented on engagement in EI services as a non-linear process and argued for the need of services to respond to patients in relation to stages of treatment, individual needs and developmental factors. Qualitative research has also highlighted the varying patterns of disengagement in EI services and disengagement being the product of inadequate support given by non-flexible mental health services (Tindall et al., 2020). Future research should focus on experiences from individuals with FEP and their

families to help inform patient-orientated definitions of engagement and reduce the current bias associated with clinical rated tools and service led definitions of engagement.

In terms of predictors of engagement and disengagement, only lack of medication adherence emerged as a strong predictor. This finding is perhaps unsurprising given that lack of medication adherence is likely indicative of poor treatment engagement in general. However, reasons behind poor medication compliance and subsequent disengagement are complex. It has been postulated that individuals may perceive treatment as being focussed around medication in EI services and once they have stopped complying with medication, other treatments are felt unnecessary (Maraj et al., 2018). Beliefs around medication can also affect medication compliance. In a qualitative study of patients with schizophrenia, external factors and coercive measures were found to influence use of medication and early non-adherence was explained by stigma related to medication use and lack of belief in illness models communicated by service providers (Tranulis et al., 2011). Exploration of service users' beliefs around medication and shared decision is therefore an essential step in supporting individuals with FEP using EI services.

The review found that in general sociodemographic variables were not predictive of disengagement. Ethnicity was however found to be significant predictor of disengagement amongst a Hong Kong cohort (Zheng et al., 2013). This was theorised to be the result of specific ethnic, cultural and religious differences between Malay and Chinese populations with possible higher tolerance of mental illness and different health beliefs seen amongst Malay families, subsequently impacting upon engagement. However, the lack of research investigating the role of ethnicity and culture makes comparison difficult. Anderson et al., (2014) found ethnicity was associated with differences in help seeking behaviours and models of illness in FEP, and non-European immigrants have been found to underuse mental health services (Whitley et al., 2006). Further research is warranted to increase our understanding of ethnic and cultural factors in FEP populations.

Inconsistent findings were found regarding the impact of clinical factors on engagement and disengagement. Interestingly, there was some evidence for higher symptom severity and better engagement (Solmi et al., 2019; Chan et al., 2014) and hypothesised that such individuals could be more motivated to engage or are encouraged to engage by family and clinicians to help ensure compliance to treatment.

Over half the studies in the review investigated the role of diagnosis on levels of engagement. Interestingly, one study found those with a diagnosis other than schizophrenia spectrum disorder were more likely to disengage and was hypothesised this was due to better earlier outcomes. Longitudinal qualitative research using an Australian FEP cohort has criticised EI services for being diagnostically led and called for services to shift away from diagnostic labels and focus on individuals need due the evolving nature of psychotic symptoms and uncertainty regarding eventual diagnosis (Tindall et al., 2020). Lack of diagnostic 'fit' in EI services has been identified as a contributing factor for both service user *and* clinician in disengaging from the therapeutic relationship, despite there being a clinical need for support. However, people who later turn out not to fit criteria for psychotic disorder may quite appropriately be disengaging from services that are unsuitable for their needs.

Strengths and Limitations

The ability to draw conclusions is inherently restricted by the quality of studies included in the review. The review benefitted from the majority of the studies using prospective methodology and the overall sample represented a natural cohort of individuals with first episode psychosis. The review had some notable limitations. Firstly the heterogeneity of the studies in terms definition and measurement of engagement made it difficult to meaningfully compare studies. Methodological differences also presented as a challenge with some studies

using case files and others having smaller sample sizes which raises questions of validity amongst some studies. The use of validated tools helps to focus engagement as a process compared to those that use 'disengagement' as an outcome. Unfortunately, only two studies used a validated tool. The current review also excluded qualitative studies and thus the perspective of service users and their families are missing. None of the reviews explored aspects of the therapeutic relationships on engagement which has been highlighted in qualitative literature as being fundamental for the success of EI services from the service users' perspective. (Tindall et al., 2018).

Although the CASP tool for cohort studies was used to appraise the papers included in the review, the tool offers no summary scores to produce an overall rating for the papers. However, Crowe and Sheppard (2011) have previously criticized summary scores in critical appraisal tools for potentially ignoring significant weaknesses in one area due to higher scores in other areas and the use of weighting schemes has been suggested to increase emphasis on more important aspects of the research. As no summary scores were produced, quality reviews of papers were not assessed for inter-rater reliability which could present as a possible limitation.

Implications for Research

There still does not exist an agreed upon definition for service engagement and disengagement. It is only when a consensus is reached that we will be able to meaningfully compare studies and identify robust contributing factors to engagement. Current measures of engagement are narrow in their focus in only representing engagement from the clinicians' perspectives. Working alongside individuals with FEP and their families is essential in order to develop tools for service engagement which represent the different stakeholders involved. Past research has commented on times during EI treatment which may be more sensitive to disengagement such as in the early stages and towards the end of treatment (Conus et al.,

2010). This is an important consideration in future research if we are to understand the mutli-faceted nature of engagement. Only few studies in the current review commented on re-engagement after initial drop-out which helps to highlight engagement as a non-linear process. Further research on reasons why individuals re-engage is an important next step in understanding the engagement and enhancing potential for recovery. Finally, engagement is multi-faceted and it is likely that many complex factors are at play when an individual is at risk of poorer engagement. Consideration of the interplay of complex service, system and cultural factors on service engagement warrants further attention (Lal & Malla, 2015).

Implications for practice

The evidence reviewed suggested that disengagement in EI services varied between 11.7% and 56.3% amongst individuals with FEP. These rates are much more variable than previously suggested (Doyle et al., 2014) and likely a result of heterogeneity in definitions and measurement of engagement. The current review highlighted medication non-adherence as one of the most robust predictors of disengagement. Services should invest in discussion surrounding service users health beliefs regarding medication and treatment in general, to help enhance service engagement. Reports of contradictory findings of predictors of engagement and disengagement call for qualitative research for disengagement and also highlight that each experiences of engagement in EI services is likely unique to the individual. This suggests the need for tailoring support to the particular needs of the person and working with individuals and their families to develop a shared formulation with consideration of their ethnicity, culture and specific life experiences, which should also takes into account how the person with psychosis views their difficulties. Those studies which looked at the impact of ethnicity on engagement highlighted the need for services to consider different cultural frameworks. People from ethnic and other minority backgrounds may find it difficult or challenging finding therapists who share similar cultural frameworks for

understanding mental illness and psychosis. It is important that such frameworks are represented, or at the very least understood, in EI services.

Conclusions

Service engagement and disengagement is a complex phenomenon which we are yet to fully understand with challenges in measuring and defining the phenomenon making it difficult to compare findings across studies and research investigating predictors of disengagement are inconsistent in their results. Previous systematic review highlighted lack of family involvement and substance abuse as robust predictors. Our findings are consistent with research which indicates substance abuse as robust predictor however evidence for family involvement was lacking.

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Chapter 2 Major Research Project

Service Engagement in First Episode Psychosis: A Prospective Study

7250 (including tables, figures, references)

Prepared in accordance with Early Intervention in Psychiatry (see appendix 1:1)

Plain English Summary

Title

Service Engagement in First Episode Psychosis: A Prospective Study

Background

Engagement in early intervention services is crucial for improving the clinical outcomes in people with first episode psychosis. It has been suggested that around 30% of young adults with first episode psychosis disengage from early intervention services. This is a cause for concern given that disengagement is associated with slower recovery, increased hospitalisation and increased risk of relapse. Our understanding of the factors that are associated with engagement is still poorly understood. Increasing our understanding of factors which predict engagement may help to target intervention to encourage better engagement in first episode psychosis and improve outcomes.

Aims and Questions:

To investigate predictors of engagement in first episode psychosis. The research questions include:

1) What are the demographic and clinical characteristics of individuals with first episode psychosis at the point of acceptance to an early intervention service?
2) What are the associations between engagement, service attachment and carers burden of care at 12-weeks following entry to the service?
3) What are the baseline demographic, clinical and psychiatric factors that predict service engagement at 12 and 26-weeks?
4) Does engagement at 12 and 26-weeks predict psychiatric recovery at 12 months follow-up?

What the study involved

The study involved gathering data from routinely collected assessments of individuals with first episode psychosis and their carers. These assessments were collected as part of an early intervention service integrated care pathway. This data was then analysed to help answer the research questions.

Results

At 12-weeks the severity of positive and cognitive disorganisation symptoms, and clinician rated lack of insight at baseline were associated with poorer levels of clinician rated engagement. We also found that carers' burden of care was associated with poorer engagement. Additionally, having a higher number of adverse childhood experiences before age 16 was also associated with lower levels of engagement. We did not find evidence that demographic or psychiatric factors at entry to the service were predictive of engagement at 12-weeks or 26-weeks. We did however find that a lack of psychiatric insight at entry to the service was associated with poorer engagement at 12-weeks. Finally, clinician rated engagement at 12 weeks predicted psychiatric recovery at 12 months follow-up.

Conclusions

Clinicians in early intervention services are well placed to identify those who present with lower levels of engagement at earlier stages of treatment and at risk of poorer psychiatric outcomes at a later stage. This has implications for treatment planning. Those who lacked insight, as rated by clinicians, were also at increased risk of clinician rated poorer engagement. Early intervention services should invest in developing novel approaches to try and increase engagement in people who lack insight to their diagnosis.

Word Count: 449

Abstract

Aims:

The effectiveness of early intervention (EI) services for people with first episode psychosis is dependent on meaningful service engagement. Difficulties with engagement in EI services increases risk of drop out which has implications for poorer functioning and poorer clinical outcomes. The purpose of the current study was to explore associations between engagement, clinical, and relational variables, and to investigate factors that predict service engagement in an early intervention service for first episode psychosis.

Methods:

The study gathered prospective routine date from an early intervention service using a naturalistic cohort of 83 individuals with first episode psychosis in Scotland, UK. Cross sectional associations between engagement, attachment, and carer's burden of care were explored. Sociodemographic, clinical and psychiatric predictors of engagement were examined using hierarchical and stepwise regression.

Results:

Poorer clinician engagement as measured by the service engagement scale (SES) was associated with greater positive symptoms and greater disorganisation, poorer insight, more effortful caregiving and higher number of adverse childhood experiences. In regression analysis, only lack of insight predicted engagement at 12-weeks. We found that engagement scores at 12-weeks predicted engagement at 26-weeks. Additionally, engagement scores at an earlier point of treatment were predictive of psychiatric recovery at 12-month follow-up.

Conclusions:

Our findings suggest that clinicians in early intervention services are well placed to identify those who are at risk of poorer engagement and subsequent poorer psychiatric outcomes which has implications for treatment planning. Additionally, people who lacked insight into their diagnosis of psychosis and need for treatment, as rated by clinicians, were rated with poorer levels of service engagement. This may reflect clinicians framework of psychosis and mental illness and might suggest the need for clinicians to work within the patients own beliefs of their experiences and framework of mental illness to help increase engagement.

Key words: Early intervention, engagement, first episode psychosis, predictors, schizophrenia

Word Count: 248

Introduction

Psychosis and associated disorders are debilitating conditions associated with poorer life expectancy, morbidity and lower quality of life (BPS, 2015). Incidence of psychotic disorders in the population has been reported as 26.6 per 100,000 with higher rates amongst men and ethnic minority populations (Jongsma et al., 2019). Each individual's experiences of psychosis are unique and can include hallucinations, delusions, cognitive and interpersonal difficulties and changes in mood. Such experiences can be distressing and disabling, particularly when experienced for the first time. The complex interplay of biopsychosocial factors often underlies experiences of psychosis with reaction to stressful and traumatic life events often playing a pivotal role (Lataster et al., 2012). Early intervention (EI) services for first episode psychosis (FEP) have been shown to be clinically and cost-effective in managing the critical early stages of psychosis (McCrone et al., 2010) Such services are based on the evidence that a longer duration of untreated psychosis (DUP) is associated with poorer clinical and functional outcomes (Marshall et al., 2005) and that early intervention is shown to be superior to treatment as usual (Correll et al., 2018).

Disengagement from EI services is associated with negative outcomes including a more chronic course of illness, increased need for hospitalisation and higher levels of functional disability (Kane et al., 2012). Poor clinician rated engagement in EI services has also been linked with higher levels of positive and negative symptoms, and poorer premorbid social adjustment (Macbeth et al., 2013). Groups previously associated with higher likelihood of disengagement include those with comorbid substance misuse and those with less family support (Doyle et al., 2014). Incidences of FEP are much higher in people from black and minority ethnic (BAME) backgrounds in the UK (Fearon et al., 2006) with complex patterns of discrimination making it less likely that these groups will seek help (Nicholls et al., 2007).

Engagement in mental health services is generally poor (O'Brien et al., 2007) and particularly concerning amongst young adults with FEP who have been identified as a challenging population to engage (Dixon et al., 2016). Specialist support offered by EI services typically involves intensive case management delivered by a multidisciplinary team with a focus on fostering a therapeutic relationship with the individual to increase the likelihood of success and engagement in recovery. The relationship between the individual and service provider is an important focal point in providing treatment and qualitative research has identified a strong therapeutic alliance as integral to the success of any intervention amongst individuals with FEP (Tindall et al., 2018).

Poor clinician rated engagement in EI services has also been linked with higher levels of positive and negative symptoms, and poorer premorbid social adjustment (Macbeth et al., 2013). It has been reported that approximately a third of people with FEP disengage from services, with rates of disengagement ranging from 20.5% to 50% (Doyle et al., 2014). However, reported rates are inconsistent. An Australian study by Kim and colleagues (2019), which employed robust measures using a large epidemiological cohort (n=700) of treated cases of FEP, found the rate of disengagement higher than previously reported with over half a cohort (56.3%) disengaging. In contrast, a prospective study by Zheng et al., (2013) using a cohort of FEP in Singapore (n=775) reported low disengagement rates of 14% over a two-year period. However, participants with a history of substance abuse were excluded from their sample despite this being a widely accepted predictor of disengagement in EI services (Doyle et al., 2014). Direct comparison between studies is also made difficult by heterogenous definitions of engagement and differences in methodological approaches. For example, whilst Zheng and colleagues (2013) included those who have moved out of the area as 'disengaged,' Kim and colleagues did not (2019). It is possible that cultural differences across samples also contribute to varying levels of disengagement. Chan et al., (2014) studying disengagement in a FEP sample from Hong Kong (n=700) and including

participants with substance abuse, found low rates at 13%. However, the level of substance abuse in their sample was much lower to that of FEP populations in Western countries.

A recognised problem is the lack of consensus on a gold standard definition of "engagement" or "disengagement" (Doyle et al 2014; Reynolds et al., 2019) and studies are often criticised for viewing these as two concrete dichotomies (Reynolds et al., 2019) which fail to capture multi-faceted nature of engagement. For example, one of the most common measures reported for disengagement is 'dropping out' of treatment (Lal & Malla, 2015) which suggests that engagement is an outcome rather than a process. Few studies report on the dynamic nature of engagement or that individuals can disengage and re-engage a number of times throughout their care. For example, in a prospective cohort, Kim et al. (2019) found that 85.5% of those who dropped out of treatment later re-engaged.

Engagement is a complex phenomenon and has been described as more than that of a physical presence, encompassing factors such as "acceptance of a need for help, the formation of a therapeutic alliance with professionals, satisfaction with the help already received and a mutual acceptance and working towards shared goals" (O'Brien et al, 2009). Definitions of engagement amongst the research literature differ between quantitative and qualitative studies. Within the qualitative research, there is a real emphasis of the therapeutic relationship (Tindall et al., 2018; Loughlin et al., 2019) and the integration of this within EI services to enable continued engagement. Farrelly and colleagues (2016) exploring joint crisis planning between service users and clinicians found that the clinicians' goals were often at odds to that of the service user. Clinicians motivations to comply with organizational requirements, particularly in line with mitigating risk, often undermined the therapeutic relationship. An individuals' desire to engage with an EI service is likely motivated by how they perceive the service and support offered to them with evidence showing disengagement can arise from a lack of shared purpose and response to individual circumstances, and inadequate mental health service systems in EI (Tindall et al., 2020).

Family and carers can play a critical role in supporting individuals experiencing FEP in their recovery (Lester et al., 2011). However, they too can be adversely impacted by FEP by experiencing high levels of distress and burden, particularly when compared to carers of those with long term complex physical conditions (Magiliano et al., 2006). A UK study exploring distress in carers of FEP found associations between higher carer burden and compulsory admission of individuals with FEP, particularly amongst black Caribbean groups (Boydell et al., 2014). Family intervention in EI services, through supporting families to understand and respond appropriately to psychosis, is a crucial aspect of care proven to improve outcomes and reduce relapse rates (Knapp et al., 2014).

A recent systematic review reported that only four out of thirty studies under review used a valid measurement tool to assess engagement (Reynolds et al., 2019). Some of the current validated questionnaires available for measuring service engagement include the Service Engagement Scale (SES; Tait et al., 2003) the Service Engagement Measure (SEM; Hall et al., 2001) and the Singh-O'Brien Level of Engagement Scale (SOLES; O'Brien et al, 2009) which offer clinician rated service engagement. Although helpful to have validated tools to measure engagement, the current tools that are available are clinician rated and therefore do not consider the service user's view in engagement which is paramount if we are to fully understand factors that contribute to engagement in FEP.

A challenge when reviewing the literature is that lack of clarity regarding time frames used to define disengagement (Reynolds et al., 2019). When validated tools are not used, it is often unclear whether time frames are arbitrary, or reflect a number of missed appointments that reach a subjective limit of 'disengagement.' Stage of recovery is another important consideration when assessing disengagement which is often overlooked; for example, an individual who disengages when acutely unwell is somewhat different to a person who disengages towards the end of their treatment following improvement in clinical outcomes. Without the use of a comparable outcome measures or an agreed upon definition of engagement, our understanding of engagement remains an ongoing challenge

in terms of being able to make meaningful comparisons between studies and generate conclusions on the dynamic nature of engagement in early intervention services.

Factors associated with service engagement in FEP are still poorly understood; however, there is growing literature examining associated predictors. Doyle and colleagues (2014) systematically reviewed ten articles and identified comorbid substance abuse and lack of family involvement or support as being the most robust predictors of disengagement in FEP. Such findings are echoed in more recent literature indicating substance abuse as a predictor of disengagement (Kim et al., 2019; Solmi et al., 2017, Lau et al., 2017) and lack of family involvement (Leclerc, 2015) increasing risk of disengagement. Lack of employment, education and training (Kim et al., 2019), duration of untreated illness (Solmi et al., 2018), beliefs about the cause of mental illness (Kim et al., 2019) have also been linked with disengagement from EI services. However, there lacks consensus regarding severity of symptoms and there are often contradictory findings (Doyle et al., 2014).

There is inconsistent evidence regarding the influence of black, asian and minority ethnic (BAME) status on levels of engagement with some studies showing greater disengagement in BAME groups (Wang, 2007; Zheng et al., 2013) whilst other have not (Solmi et al., 2018; Casey, 2016). Difficulties exist regarding meaningful comparison of the influence of ethnicity in engagement due to the lack of studies exploring specific ethnic and cultural factors. However, there is evidence that compared to White British populations, Black Caribbean and Black African patients experience worse clinical outcomes with regards to treatment for psychosis with persistent social disadvantages in Black Carribean and Black African patients contributing to such health inequity (Morgan et al., 2017). A recent meta-analysis (Anderson et al., 2014) found that ethnicity may have an impact on care pathways due the influence of help seeking behaviour and models of illness; however, studies in this area were sparse making conclusions difficult. A systematic review and meta-analysis by Schoer and colleagues (2019) found no differences in DUP for BAME compared to White groups; however Black-African groups had a shorter DUP whereas Black-

Carribean groups had a longer DUP compared to White groups suggesting the need for informed targeting of EI for minority populations. Maraj and colleagues (2018) investigating immigrant status on engagement found differences in predictors of engagement between first and second generation immigrants in a cohort of FEP in Canada. Immigrants were found to be three times more likely than non-immigrants to disengage from treatment in EI services (Ouellet-Plamondon et al., 2015). These are notable findings given that immigrants are at a higher risk of developing a psychotic disorder than non-immigrants (Bourque et al.,2011), although less likely to access care (Thomson et al 2015).

Considering the poorer outcomes associated with poorer engagement with EI services, it is vital that we understand the predictors of engagement to ensure tailoring of assertive outreach and improved delivery of FEP services. At present, there is a lack of consensus regarding the clinical correlates and predictors of service engagement, which in part reflects differing methodologies such as retrospective versus prospective designs, and the use of cross-sectional data which captures engagement as an outcome rather than a process. The current study was designed to provide a prospective study of service engagement at 12 and 26 weeks, and psychiatric recovery (as measured by decrease of psychiatrtic symptoms) at 12 months in a cohort of FEP using specialist EI services. We also explored cross sectional associations of service engagement with clinical outcomes, service attachment and carers' distress. We tested the following hypotheses:

1) Poorer clinician rated engagement at 12-weeks will be correlated, cross sectionally, with greater overall symptoms, lower levels of service attachment, higher reports of carer distress and more adverse childhood experiences.
2) Severity of psychiatric, mood and anxiety symptoms at entry to the service will predict service engagement at 12 and 26-week follow-up.
3) Clinician rated service engagement at 12 and at 26-week follow-up will predict psychiatric outcomes at 12-month follow-up.

Methods

Methods

The study was a prospective cohort study of individuals with a first episode psychosis using a specialist early intervention service in NHS Greater Glasgow & Clyde (NHSGG&C), Scotland. The original project received appropriate NHS ethical (11/AL/0247) and managerial (GN11CP130) approvals to proceed prior to data collection.

Participants

Participants were individuals with a first episode psychosis in the ESTEEM First Episode Psychosis Service in NHSGG&C who provided their informed consent to participate. The Esteem service works with those aged between 16-35 year old in the NHS Greater Glasgow and Clyde are for up to two years, and provides MDT support to the individual with psychosis and their family and supporters. Mainly urban and inner city with higher levels of deprivation. Serves a population of 1.2 million. Largest health board.

Participants were individuals presenting with a first episode of affective or non-affective psychosis as defined by the DSM-IV criteria (American Psychiatric Association, 1994). Exclusion criteria included individuals who did not consent to take part in the study. Participants and their carers were asked for their informed consent to participate in the study when referred to the early intervention service.

Measures

Data were taken from measures that are routinely collected by mental health staff as part of an integrated care pathway at entry to the service, 12-weeks, 26-weeks and 1-year follow-up.

Positive and Negative Syndrome Scale (PANSS, Kay, Flszbein & Opler, 1987) is a 30 item semi-structured interview which measures current symptoms on a Likert scale from minimal (1) to extreme (7). The five-factor scoring method (Van der Gaag et al., 2006) was used as this offers a better representation of the dimensional structure of the PANSS data compared to the original three sub-scale structure (Wallwork et al., 2012). The five subscales of the PANSS cover the following symptomology; positive, negative, cognitive/disorganisation, excitement, and distress. The PANSS has a high internal consistency, adequate external validity and test-retest reliability (Kay et al., 1987; 1998), and good inter-rater reliability (Peralta & Cuesta, 1994). For analysis of insight, the insight item (D7) from the PANSS was included on top of the five subscales. Higher scores on the PANSS indicates higher severity of symptoms on subscales, and less acceptance of illness and need of treatment for the insight item. PANSS was administered at entry to the service, 12 weeks and 26 weeks, and at 12 months routinely by clinicians in the ESTEEM service. The internal consistency for all PANSS items in the current study was α =0.895 (95%CI=0.859-0.926); however, internal consistency for each subscale varied with the following results; PANSS positive α = 0.436 (95%CI=0.222-0.607), PANSS negative α=0.905 (95%CI=0.869-0.934), PANSS cognitive disorganisation α=0.883 (95%CI=0.840-0.918) PANSS emotional distress α = 0.658 (95%CI=0.533-0.759). Variations across PANSS subscales was likely due to the use of routine data and administration of the measures by different clinicians in the ESTEEM service. All clinicians attended a one-day training in the use and scoring of the PANSS and participated in calibration sessions. Clinicians were followed up by a Research Assistant who provided support in ensuring ratings were made on time and to answer questions about scoring.

Hospital Anxiety and Depression Scale (HADS, Zigmond and Snaith, 1983) is a widely used self-report questionnaire with 14 items to assess distinct dimensions of anxiety and depression in non-psychiatric populations. Both anxiety and depression subscales of the measure have high internal consistency amongst individuals diagnosed with schizophrenia (Sellwood et al., 2013). The HADS was administered to individuals at entry to the service, at 12 and 26 weeks and at 12 months by clinicians in the ESTEEM service. Internal consistency for anxiety and depression subscales in the current study were with α=0.858 (95%CI=0.803-0.9.03) and 0.867 (95%CI=0.814-0.908) respectively

Involvement Evaluation Questionnaire (IEQ, Schene et al., 1993) is a 31-item questionnaire completed by caregivers. Items have four subscales measuring; tension, supervision, worrying and urging. The internal consistency of IEQ subscales are satisfactory in other studies (Wijngaarden et al., 2000). The IEQ was administered to carers of individuals using the service by ESTEEM clinicians at entry to the service, 12 and 26 weeks and at 12 months. Internal consistency in the current study was α=0.815 (95%CI=0.707-0.897) and ranged from α = 0.735 to α = 0.858 across subscales.

Service Engagement Scale (SES) – Tait et al., 2002

These SES is a 14-item clinician completed scale to asses overall engagement with services. Items assess four subscales; availability, collaboration, help-seeking, and treatment adherence. The scale has good reliability and discriminant validity, α=0.76-0.90 for subscales (Tait et a., 2014). The SES was completed by clinicians at 12 and 26 weeks and at 12 months. The SES is utilised by the service to help identify where clinicians are struggling to engage service users and directly informs team formulation discussions at 12-weeks following service entry. Internal consistency of the SES in the current study was α=0.88 (CI 95%=0.837-0.916). The following internal consistency was reported for SES subscales;

availability α=0.583 (95%CI=0.399-0.717) collaboration α=0.855 (95%CI=0.791-0.902) help seeking α=0.871 (95% CI=0.818-0.913), treatment adherence α=0.848 (95%CI=0.786-0.896).

Service Attachment Questionnaire (SAQ Goodwin et al., 2003) is a self-report measure assessing the security of attachment to staff members, with a higher score indicating greater security attachment to the service. It has good internal consistency (Blackburn et al., 2010) and test-retest reliability (Goodwin et al., 2003). The SAQ was completed by participants at 12 and 26-weeks and 12 months. The internal consistency of the SAQ in the present study was lower than what would be expected α=0.48 (95%CI=0.143-0.729).

Adverse Childhood Experiences measure (ACES) was adapted from *Adverse Childhood Experiences Study Questionnaires (ACES)* (Felitti et al., 1998) which is a 25-item self-report measure that assesses the relationship of health risk behaviour and disease in adulthood to the breadth of exposure to childhood emotional, physical, or sexual abuse, and household dysfunction during childhood. A checklist was developed by the service for staff to routinely complete as part of their assessment pathway during the first 12-weeks. The checklist served as a prompt for staff to routinely and sensitively enquire about adverse early childhood experiences.

Data Analyses

Sample size and power

Power analyses were conducted using Gpower 3.0 on Mac to calculate effect sizes for multiple regressions to predict engagement scores at 12-weeks and 26-weeks, and psychiatric outcomes at 12-months. For predicting engagement at 12-weeks using nine predictor variables; age, gender, no education employment or training (NEET), living alone,

black, asian and minority ethnic (BAME), PANSS insight, PANSS total, and HADS anxiety and depression scales, and assuming a range of medium to large effect sizes from 0.15 to 0.35 and α=0.5, the power was estimated to be between 0.62 and 0.97 (see appendix 2.2). There were n=71, n=75 and n=60 participants' full data available for each of the planned regressions. Therefore, non-significant clinical variables were omitted from subsequent analyses to minimise overloading regression models.

Data were analysed using SPSS version 18. Variables were checked for normality using the Kolmogorov-Smirvov test. Relationships between variables were examined using Pearson correlations for parametric data, and Spearman correlations for non-parametric data. Prior to multiple regression analyses, dependent and predictor variables were checked for multicollinearity by the examination of an inter-correlation matrix where values above 0.80, VIF > 10 (Myers, 1990) and tolerance statistics <0.1 (Bowerman & O'Connell, 1990) suggest multicollinearity was problematic. Autocorrelation was checked using the Durbin-Watson test statistic (Durbin and Watson, 1951) where values of <1 or >3 indicate residuals were correlated. Data were checked for outliers using casewise diagnostics to check for standard residuals >3 standard deviations. Cooks Distance (Cook & Weisberg, 1982) was used to check for measure of influence, where values of >1 would indicate the model was a poor fit of the data and that outliers may be present. Linearity and homoscedasticity were checked by the examination of standardised residuals scatterplots. Histograms and normal probability plots were examined to check for normally distributed residuals.

The dependent variables; clinician rated engagement and psychiatric outcomes, were entered into multiple regression analyses: hierarchical and stepwise. The hierarchical method was selected to allow variables of interest to be added to the model and to investigate the contribution of predictors that have inconsistent support in the literature regarding their relationship to service engagement in FEP. Stepwise was selected because the hierarchical models included non-significant predictors where these variables did not contribute significantly to the model.

Study variables were selected a priori based on previous research findings. The planned order of measures entered into the hierarchical regression to explore associations with service engagement at 12 weeks were; age, gender, NEET, living alone, BAME, and psychiatric severity at baseline which included; PANSS insight, PANSS total and anxiety and depression scales. This combination was repeated using service engagement at 26 weeks with the addition of 12-week SES scores as a final step in the model. Measures were entered in this order to control for demographic variables before evaluating the contribution of clinical symptoms on engagement. All predictor variables were entered for the stepwise method with 12 weeks and then 26 weeks as the dependent variable. Predictor variables 'living alone', 'NEET' and 'BAME' were coded as dichotomous variables ('yes/no').

The final regression looked to answer whether psychiatric outcomes at 12 months was associated with clinician rated engagement at 12 and 26 weeks. The planned order of measures entered here were; age, gender, NEET, living alone, and BAME status, and then; psychiatric, mood and anxiety scores at entry to the service were added, followed by service engagement at 12 and 26 weeks. All predictor variables were entered into the stepwise regression with total PANSS score at 12 months as the dependent variable. Sensitivity analyses were conducted using SES and PANSS subscales as dependent variables on their respective multiple regression models.

Results

Demographics and clinical characteristics

Of 113 people referred to the service, 2 were unable to provide informed consent, 8 were unavailable for consent and 23 declined consent to participate, leaving 83 (73.5%) participants who took part in the study. The mean age of participants was 25.64 years old (SD=5.51; IQR 20.87-30.50); 55 (66%) were male, 28 (34%) were female. Descriptive data for personal characteristics are presented in table 1.

Table 1 Summary Statistics for the sample at entry to the service (n=83)

	n (%) of total sample	Mean (SD)	Median (IQR)
Sex			
Male	55 (66)		
Female	28 (34)		
Black, Asian and Minority Ethnic (BAME)			
Yes	19(23)		
No	64 (77)		
Not in Education, Employment or Training (NEET) [*N%], n=80*			
Yes	34 (42.5)		
No	46 (57.5)		
Living alone at entry to service [*N%], n=82*			
Yes	15 (18)		
No	67(82)		
HADS Anxiety 'Caseness' [*N(%), n=74]*			
Yes	46 (55)		
No	28 (34)		
HAS Depression 'Caseness' [*N(%), n=74]*			
Yes	35 (47)		
No	39 (53)		
Childcare Responsibilities			
Yes	10 (12)		
No	73 (88)		
Age at entry to service		25.64 (5.51)	25.08 (20.87-30.50)
Number of ACES before 16 [*n=48)*		3.23 (2.61)	2.5 (1-5)
PANSS Positive Syndrome [*n=82]*		21.11(5.19)	21(18-25)
PANSS Negative Syndrome [*n=82]*		16.44 (9.18)	13 (7-42)
PANSS Cognitive/Disorganisation [*n=82]*		24.48 (10.23)	24 (18-31)
PANSS Excitement [*n=82]*		9.45 (5.26)	8 (5-13)
PANSS Emotional Distress [*n=82]*		12.34 (5.26)	13 (8-16)
PANSS Insight (D7) [*n=82]*		3.99 (1.83)	4 (3-6)
PANSS Total [*n=82]*		83.78 (24.62)	83 (67.5-100)
HADS Anxiety [*n=74]*		10.2(5.06)	9(6-14.25)
HADS Depression [*n=74]*		8.23 (5.46)	7.5(5-12)

ACES indicates Childhood Adverse Experiences; PANSS indicates Positive and Negative Syndrome Scale; HADS indicates Hospital and Anxiety Depression Scale

Engagement and Clinical Correlates

Cross-sectional correlational analysis was conducted using 12-week data to investigate associations between clinician rated engagement and symptom severity, service attachment and carers' distress. There was a statistically significant, moderate positive correlation found between engagement and positive symptoms ($r = 0.32$, $p<0.01$), cognitive/disorganisation ($r=0.35$, $p<0.01$) and insight ($r = 0.42$, $p<0.01$) suggesting participants who were rated as more difficult to engage had higher severity of positive and cognitive disorganisation symptomology, and less acceptance of illness and needing of treatment. Associations were found between more effortful care from caregivers ($r=0.32$, $p<0.05$). We found that number of adverse childhood events was associated with engagement ($r=0.35$, $p<0.05$). There were no associations between service engagement and service attachment, albeit the sample size available for the SAQ was limited ($n=27$). Correlations between engagement subscales and clinical variables are detailed in table 2.

Table 2 Correlates of Service Engagement at 12-weeks

	PANSS Positive[a]	PANSS Negative[b]	PANSS Cog Dis[a]	PANSS Excitement[b]	PANSS Emotional Distress[a]	PANSS Insight[a]	HADS Anxiety[a]	HADS Depression[a]	SAQ Total[b]	IEQ Tension[a]	IEQ Supervsion[b]	IEQ Worrying[a]	IEQ Urging[a]	IEQ Total[a]	ACE[b]
SES Total[a]	0.32**	0.16	0.35**	0.20	-0.03	0.41**	-0.20	-0.02	-0.06	0.31	0.17	0.28	0.30	0.32*	0.35*
SES Availability[b]	0.22	-0.12	-0.03	0.12	-0.06	0.10	0.81	-0.08	-0.12	0.28	0.34*	0.31*	0.25	0.36*	0.21
SES Collaboration[a]	0.25*	0.20	0.34**	0.24*	-0.11	0.32**	-0.22	-0.10	-0.07	0.35*	0.31	0.32*	0.23	0.36*	0.26
SES Help[a]	0.20	0.28*	0.32**	0.11	0.08	0.36**	-0.11	-0.13	0.14	0.15	0.09	0.16	0.10	0.15	0.37*
SES Adherence[a]	0.28*	0.04	0.23*	0.17	-0.05	0.30**	-0.26*	-0.27*	-0.8	0.17	0.04	0.07	0.14	0.12	0.24

**Correlation is significant at the 0.01 level (2-tailed); *Correlation is significant at the 0.05 level (2-tailed). [a] Pearson *r*, [b] Spearman rho. SES: Service Engagement Scale; PANSS: Positive and Negative Syndrome Scale; HADS: Hospital Anxiety and Depression Scale; SAQ: Service Attachment Questionnaire; IEQ: Involvement Evaluation Questionnaire; ACE: Adverse Childhood Experiences before age 16

Predictors of engagement at 12 and 26-weeks.

All assumptions necessary for multiple regression were satisfied, with the exception of SES scores at 26-weeks which casewise diagnostics indicated one case with a standard residual of 3.032. The decision was made not to trim the data given this standard residual was only slightly above the value of 3.

Hierarchical (blockwise entry) and stepwise multiple regression analyses were performed to examine hypotheses that severity of psychiatric, mood and anxiety symptoms at entry to the service will be correlated with service engagement at 12 and 26-weeks follow-up. The results for the multiple regression analyses for service engagement at 12 and 26-weeks are presented in table 3 and 4.

Predictors of engagement at 12-weeks

A multiple hierarchical regression was run to predict engagement at 12-weeks, controlling for demographic variables. At step 1 the following demographic variables were entered; age, gender, living along, NEET, and BAME status which gave an R^2 of 0.04 and adjusted R^2 of -0.04, and was not significant. On step 2, psychiatric, mood and anxiety symptoms were added to the model with an adjusted R^2 of 0.04 and R^2 of 0.17 which again was not significant. The full model of demographic variables, and psychiatric, mood and anxiety symptoms was not statistically significant, R^2=0.17, $F(9,61)=1.34$, p=0.23, adjusted R^2=0.04. Multiple regression results including regression coefficients are presented in table 3. Sensitivity analyses were conducted using subscales from the SES; availability, collaboration, help seeking and treatment

adherence, as dependent variables and confirmed the model was replicable as no significant predictors emerged.

When all predictor variables (*n*=13) were entered into the model, the stepwise method indicated that only PANSS insight was significant for inclusion into the model and accounted for 9.9% of the variance, with $R^{2=}0.11$, $F(1,69)=8.72$ p=<0.005, adjusted $R^2=0.10$.

Table 3. Multiple Regression Analysis for Engagement at 12-weeks (n=71)

	R	R^2	Adjusted R^2	*F*	Sig. of *F*	B (CI 95%)	β	Partial *r**
Hierarchical Model								
Age	0.20	0.04	-0.04	0.53	0.75	0.07 (-0.32, 0.34)	0.005	0.01
Gender						-0.35 (4.21, 5.51)	-0.02	-0.02
Living Along						-3.09 (-7.54, 1.37)	-0.17	-0.18
NEET						-0.28 (-3.52, 2.95)	-0.02	-0.02
BAME						-1.67 (-6.09, 2.76)	-0.10	-0.10
PANSS Insight	0.41	0.17	0.04	1.34	0.23	1.48 (0.16, 2.80)	0.38	0.28
PANSS Total						-0.03 (-0.13, 0.06)	-0.11	-0.09
HADS Anxiety						-0.15 (-0.59, 0.28)	-0.12	-0.09
HADS Depression						-0.002 (-0.40, 0.40)	0.01	0.001
Stepwise model								
PANSS Insight	0.34	0.11	0.10	8.72	0.004	1.30 (0.42, 2.17)	0.34	0.34

*The standardised regression coefficient or beta and the partial correlation are shown; PANSS: Positive and Negative Syndrome Scale; HADS: Hospital Anxiety and Depression Scale; SES: Service Engagement Scale

Predictors of engagement at 26-weeks

Multiple hierarchical regression was conducted to determine predictors of engagement at 26-weeks (table 4). As HADS anxiety and depression and PANSS total were not significant in the previous regression investigating predictors at 12-weeks, these were removed from the model. The overall model consisted of demographic variables, PANSS insight and the addition of 12-week SES scores and explained 19% of the variance and was found to be significant, $R^2=0.27$, $F(7,67)=3.54$, p<0.005, adjusted $R^2=0.19$. At step 1, demographic variables; age, gender, living along, NEET and BAME status were entered which gave R^2 of 0.03 and adjusted R^2 of -0.04 and was not significant (F=0.47, p=0.80). On step 2 when insight was added to the model R^2

was 0.07, adjusted R^2 was -0.01 and the increment of change was not significant (F=2.91, p=0.09). On step 3 when 12-week SES scores were entered into the model, R^2 was 0.27, adjusted R^2 was 0.19 and the change was significant (F=18.11, p<0.001).

When all predictors (n=7) were entered into the model, stepwise regression indicated that only SES scores at 12 weeks was significant for inclusion into the model, accounting for 22.6% of the variance, R^2=0.24, $F(1,73)$=22.62, p<0.001, adjusted R^2=0.24.

Table 4. Multiple Regression Analysis for Engagement at 26-weeks *(n=75)*

	R	R^2	Adjusted R^2	*F*	Sig. of *F*	B (CI 95%)	β*	Partial *r**
Hierarchical Model								
Age	0.18	0.03	-0.04	0.47	0.80	-0.10 (-0.33, 0.35)	0.007	0.008
Gender						-2.69 (-6.80, 1.07)	-0.16	-0.18
Living Along						0.59 (-4.81, 5,26)	0.03	0.03
NEET						1.23 (-1.94, 4.39)	0.08	0.09
BAME						0.32 (-4.45, 5.08)	0.02	0.02
PANSS Insight	0.27	0.07	-0.01	0.89	0.51	0.21 (-0.89,1.31)	0.04	0.05
12-weeks SES	0.52	0.27	0.19	3.54	0.00	0.57 (0.30, 0.84)	0.49	0.46
Stepwise model								
12-weeks SES	0.49	0.24	0.23	22.62	0.00	0.57 (0.33, 0.81)	0.49	0.49

*The standardised regression coefficient or beta and the partial correlation are shown; PANSS: Positive and Negative Syndrome Scale; SES: Service Engagement Scale

12-month psychiatric symptoms

Hierarchical multiple regression was run to determine the predictors of psychiatric outcomes at 12 months (table 5). The full model of demographic variables, baseline psychiatric scores and engagement at 12 and 26-weeks to predict psychiatric outcomes at 12-months was not significant, R^2=0.17, $F(11,48)$=0.90, p=0.55, adjusted R^2=-0.02.

When all variables were entered into the stepwise model (n=11), stepwise regression showed only 12-weeks SES scores were significant for inclusion into the model for prediction

of psychiatric scores at 12 months, accounting for 10% of the variance, R^2=0.12, F(1,58)=7.66, p<0.01, adjusted R^2=0.10.

Table 5. Multiple Regression Analysis for Psychiatric Recovery at 12-months *(n=60)*

	R	R^2	Adjusted R^2	*F*	Sig. of *F*	B (CI 95%)	β	Partial *r**
Hierarchical Model								
Age	0.16	0.03	-0.06	0.30	0.91	-0.18 (-1.39, 1.037)	-0.04	-0.04
Gender						-1.20 (-15.73, 13.34)	-0.02	-0.02
Living Along						-5.47(-22.29, 11.35)	-0.10	-0.09
NEET						0.04 (-11.99, 12.06)	0.00	0.00
BAME						2.46 (15.70, 20.62)	0.04	0.04
PANSS Insight	0.22	0.05	-0.13	0.27	0.98	-1.14 (-6.12, 3.85)	-0.09	-0.07
PANSS Total						0.11 (-0.21, 0.44)	0.12	0.09
HADS Anxiety						0.82 (-0.79, 2.42)	0.18	0.15
HADS Depression						-0.74 (-2.15, 0.67)	-0.18	-0.15
12-weeks SES	0.41	0.17	-0.02	0.90	0.55	1.03 (-0.03, 2.11)	0.33	0.27
26-weeks SES						0.91 (-2.88, 4.71)	0.08	0.07
Stepwise model n=60								
12 weeks SES	0.34	0.12	0.10	7.66	0.01	1.06 (0.29-1.83)	0.34	0.34

*The standardised regression coefficient or beta and the partial correlation are shown; PANSS: Positive and Negative Syndrome Scale; HADS: Hospital Anxiety and Depression Scale; SES: Service Engagement Scale

Discussion

The first aim of the study was to establish associations between clinician rated engagement and psychiatric symptom severity, service attachment and carers' burden of care at 12-weeks. We found that severity of positive and cognitive disorganisation symptoms, and lack of insight were associated with poorer levels of engagement and thus the initial hypothesis was partially supported. No associations were found between negative symptoms, excitement symptoms, emotional distress, anxiety or depression. Some of our findings are consistent with previous research. Macbeth et al., (2013) found poorer clinician engagement as measured by the SES was also associated with greater positive symptoms and greater psychopathology; however, the same study found associations with negative symptoms which was not evident

in the present study. Our findings reflect other research which have found associations with engagement and cognitive disorganisation (Johansen et al., 2011; Macbeth et al., 2016), and insight (Starting et al., 2009; Belvederi Murri et al., 2016).

We explored the relational aspects of engagement and found associations between more effortful caregiving from carers and poorer levels of engagement. Informal support from caregivers is invaluable in the early phase of psychosis and research has highlighted the clear benefit of a strong relationship between carers and EI services on both supporting carers to manage distress (Lavis et al., 2015) and in enhancing service user satisfaction in EI services (Lester et al., 2011). The association between carers' burden of care and service engagement has not previously been noted in the literature. We found that that higher number of ACES were associated with poorer engagement. It has been theorised that ACES in childhood may hinder the development of attachment security (Bowlby, 1990) and further work is needed to understand the contribution of ACES on relational aspects of engagement. We were interested in the associations between service attachment and engagement however no significant findings emerged. The lack of association between clinicians' ratings of service engagement and service users' ratings of service attachment, albeit with a small sample size, merits further research in the future.

Secondly, the hypothesis that severity of psychiatric, mood and anxiety symptoms at entry to the service would predict engagement at 12 and 26-weeks was rejected. This is consistent previous findings in FEP (Lau et al., 2017; Chan et al., 2014; Stowkowy et al., 2012). Evidence for clinical predictors of engagement has been inconsistent in the FEP literature (Doyle et al., 2014) and whilst some studies have noted the contribution of positive symptoms (Lecomte et al., 2008, Turner et al., 2007) and negative symptoms (MacBeth et al., 2013) on engagement,

others have not (Maraj et al., 2018; Lau et al., 2017). Stepwise regression found that psychiatric insight was predictive of engagement at 12-weeks, albeit the association was small. This finding is consistent with research which has suggested insight as being one of the more consistent predictors of engagement demonstrated in the literature (Turner et al., 2007, Zheng et al., 2013 Doyle, 2014). However, others have found no association (Conus et al.,2008; Stowokowy et al., 2012). Insight has an array of different theoretical underpinnings in the psychosis literature (McCormack et al., 2013) and different measurements are employed to capture this construct which may explain some of the discrepancies amongst the research.

The hierarchical regression model was not significant in predicting engagement at 26-weeks and effects of insight was no longer present in the stepwise model, rather 12-week SES scores were predictive of engagement at 26-weeks. Lastly it was hypothesised that clinician rated engagement at 12 and 26-weeks would predict recovery at 12-months. Hierarchical regression did not support this hypothesis; however, the stepwise model suggested clinician rated engagement at 12-weeks predicted psychiatric recovery at 12-months. This suggests clinician rated engagement during this time frame can be a useful tool in identifying those at risk of poorer outcomes and adapting treatment plans accordingly. We found that clinician rated service engagement accounted for 10% of the variance in psychiatric recovery. Interestingly, the effect found here was larger than that reported in meta-analyses for therapeutic alliance on outcomes in adult psychotherapy populations (r=0.274, Del Re et al., 2012). Clinician rated engagement therefore could be a useful tool when formulating treatment plans to increase treatment outcomes for those at risk of poor engagement and subsequent poorer outcomes.

Strengths and Limitations

Strengths of the present study include clinician engagement with routine collection of data, prospective design, use of a validated engagement tool, and good rates of consent (79%) However, the study should by reviewed in light of some limitations. Firstly, the current sample size was relatively small which has implications for statistical power. Although we used a validated tool for measuring engagement the SES is clinician rated, and it is unclear to the extent to which individuals with psychosis and their families agree with the construct used to measure service engagement. It is of interest that we found no association between clinician rated service engagement and service user ratings of service attachment. This finding merits further investigation. It was interesting that with the exception of insight, no other demographic or clinical variables were predictive of engagement or recovery. It should be noted that the measure used to assess insight was clinician rated, and therefore may not be reflective of, or differ quite significantly from, the patient's own beliefs about mental illness. For example, patients who do not share the same understanding of psychosis, or reject their diagnosis may be viewed as 'lacking insight' by clinicians. Patients may view their psychosis as helpful or even spiritual which might also have an impact on their motivation to engage with services. The lack of patient input on their views of illness and their motivation to engage in treatment is therefore a limitation in the current study.

We found weak evidence for more effortful care and higher number of ACES being associated with poorer engagement; however, the cross-sectional design limits the conclusions that can be drawn from this. Longitudinal and mixed-methods approach investigating relational aspect of engagement in EI services would help increase the validity of these findings.

We did not collect demographic data on clinicians who worked at the ESTEEM service and such data would have been helpful to comment on issues such as diversity of the staff team. It is important that staff can represent, or are familiar with, the various cultures of those using their service, and that people from ethnic and minority backgrounds can work with clinicians who share similar cultural frameworks.

Although rates of consent into the study were 79%, those who did not consent might have been rated by staff as having poorer levels of engagement. Therefore, it is possible that engagement levels are overestimated in those who use EI services in the given catchment area.

Finally, the study lacks input from different stakeholders and thus results largely reflect the clinician's framework of understanding psychosis and mental illness. Qualitative accounts from service users and their supporters would help further our understanding of individuals reasons for engagement in EI services.

Implications

The findings of this study have implications for both research and clinical practice. A major limitation of the current study, and other studies in the research literature that investigate engagement in EI services, is that engagement from the service user perspective is largely unheard. Further work is needed to understand how people with FEP and their families experience engagement which should help bridge the inherent bias associated with clinician rated engagement scales. Factors such as disempowerment, stigma, and changes in clinicians have been identified as common reasons for disengagement from the perspective of the service user (Tindall et al., 2020) and it is important that such voices are incorporated into how we measure engagement in future studies.

Previous research has been inconsistent in identifying robust predictors of engagement and this has been reflected in our lack of findings. This may have implications for future research in in terms of alternative methodologies to investigate engagement. Emerging research using complexity science to understand mental health has challenged traditional clinical trials and their focus on 'cause and effect.' Complexity science argues the necessity to study the complex systems which give rise to psychopathology in order to explain, predict and successfully intervene (Fried & Robinaugh, 2020). Consideration of such methodologies may help enhance our understanding of the complex interplay of biopsychosocial systems that may influence engagement in FEP.

In terms of clinical implications, our findings that stronger engagement in the early stages of treatment is linked to better psychiatric recovery reinforces opportunities to improve outcomes through the therapeutic relationship. This is reassuring given the already strong focus therapeutic alliance in EI services. We found that insight was a predictor of poorer clinician rated engagement in EI services. Individuals who score higher on insight measures may not necessarily agree with their diagnosis and may not wish to engage in services. Past research has shown that clinicians tend to struggle with individuals who do not 'fit' with the service model which can lead to uncertainty around the purpose of engagement and decreased confidence in supporting such individuals (Tindall et al, 2020). There is a need for clinicians to step outside diagnostic labels in such cases and find novel ways to engage people who present with lower levels of insight.

Conclusion

In this study using routine data from a naturalistic cohort of FEP patients, severity of positive and cognitive disorganisation symptoms, and lack of insight were associated with poorer levels of engagement. We also found weaker evidence for more effortful care and higher number of ACES being associated with poorer engagement. In regression analysis, lack of insight was found as a predictor of poorer clinician rated engagement at 12-weeks, and engagement at 12-weeks was predictive of later engagement at 26-weeks. We also found clinician rated engagement at 12-weeks to be predictive of psychiatric outcomes at 12-month.

Individuals with poor levels of engagement may be at risk of disengagement from EI services which may lead of future relapse and poorer functioning (Conus et al., 2017). These findings suggest staff are well placed to identify those at risk of low engagement and subsequent poorer recovery which has implications for treatment planning. Additionally, our findings add to the existence evidence that suggest lack of insight is a marker for poorer engagement, calling for novel approaches to help engage such individuals.

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Appendix

Appendix 1:1 Author Guidelines for Submission to Early Intervention in Psychiatry

Author Guidelines

Sections

1. SUBMISSION

Thank you for your interest in *Early Intervention in Psychiatry*. Authors should kindly note that submission implies that the content has not been published or submitted for publication elsewhere except as a brief abstract in the proceedings of a scientific meeting or symposium.

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v. Abstract and keywords;
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vii. Acknowledgements;
viiii. Conflict of interest statement;
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xi. Figure legends;
xii. Appendices (if relevant).

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Authors should use the following subheadings to divide the sections of their manuscript: Introduction, Methods, Results and Discussion.

Acknowledgments

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Book

Bradley-Johnson, S. (1994). *Psychoeducational assessment of students who are visually impaired or blind: Infancy through high school* (2nd ed.). Austin, TX: Pro-ed.

Internet Document

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Tables should be self-contained and complement, not duplicate, information contained in the text. They should be supplied as editable files, not pasted as images. Legends should be concise but comprehensive – the table, legend, and footnotes must be understandable without reference to the text. All abbreviations must be defined in footnotes. Footnote symbols: †, ‡, §, ¶, should be used (in that order) and *, **, *** should be reserved for P-values. Statistical measures such as SD or SEM should be identified in the headings.

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Authors will receive an e-mail notification with a link and instructions for accessing HTML page proofs online. Page proofs should be carefully proofread for any copyediting or typesetting errors. Online guidelines are provided within the system. No special software is required, all common browsers are supported. Authors should also make sure that any renumbered tables, figures, or references match text citations and that figure legends correspond with text citations and actual figures. Proofs must be returned within 48 hours of receipt of the email. Return of proofs via e-mail is possible in the event that the online system cannot be used or accessed.

Early View

The journal offers rapid speed to publication via Wiley's Early View service. **Early View** (Online Version of Record) articles are published on Wiley Online Library before inclusion in an issue. Note there may be a delay after corrections are received before the article appears online, as Editors also need to review proofs. Once the article is published on Early View, no further changes to the article are possible. The Early View article is fully citable and carries an online publication date and DOI for citations.

8. POST PUBLICATION

Access and sharing

When the article is published online:

• The author receives an email alert (if requested).
• The link to the published article can be shared through social media.
• The author will have free access to the paper (after accepting the Terms & Conditions of use, they can view the article).
• The corresponding author and co-authors can nominate up to ten colleagues to receive a publication alert and free online access to the article.

Print copies of the article can now be ordered (instructions are sent at proofing stage).

Article Promotion Support

Wiley Editing Services offers professional video, design, and writing services to create shareable video abstracts, infographics, conference posters, lay summaries, and research news stories for your research – so you can help your research get the attention it deserves.

Measuring the Impact of an Article

Wiley also helps authors measure the impact of their research through specialist partnerships with **Kudos** and **Altmetric.**

9. EDITORIAL OFFICE CONTACT DETAILS

Professor Patrick McGorry, Editorial Office, *Early Intervention in Psychiatry*
C/O Wiley
155 Cremorne St
Richmond, Victoria, 3121
Australia
Email: **eip.eo@wiley.com**

Author Guidelines updated 18 March 2019

Appendix 2.2 Power Calculation

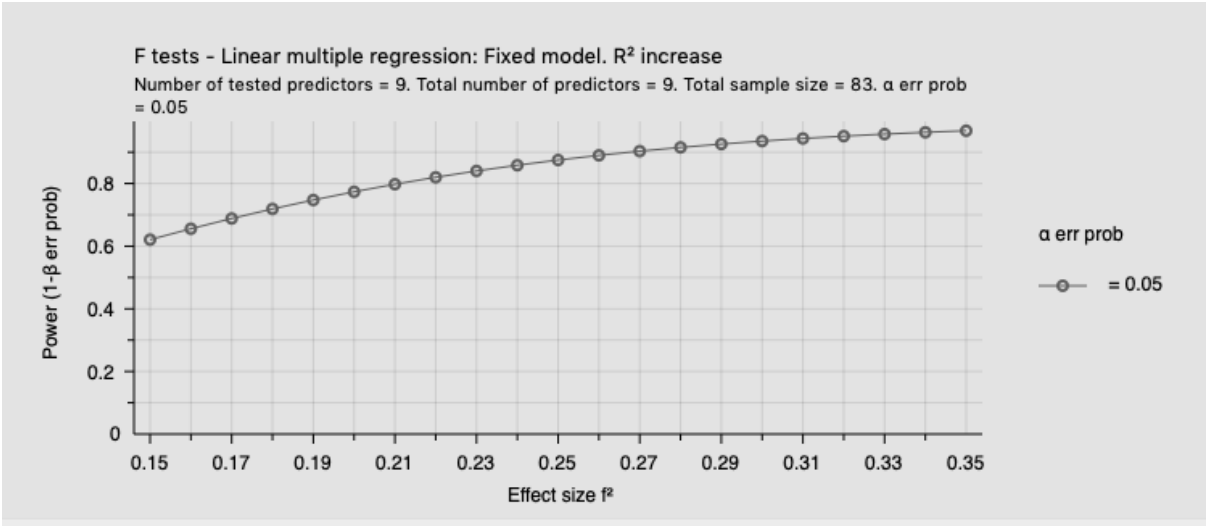

Figure 2: Post hoc power calculation for multiple regression (*n*=83)

Appendix 2.3 Ethical Approval for Access to Secondary Data

Administrator: Mrs Elaine O'Neill
Telephone Number: 0141 314 4001
E-Mail: elaine.o'neill2@ggc.scot.nhs.uk
Website: https://www.nhsggc.org.uk/about-us/professional-support-sites/research-development/

Clinical Research & Innovation
Dykebar Hospital, Ward 11
Grahamston Road
Paisley, PA2 7DE
Scotland, UK

01 October 2020

Prof Andrew Gumley
Gartnavel Royal Hospital
1055 Great Western Road
Glasgow G12 0XH

NHS GG&C Board Approval

Dear Prof A Gumley,

Study Title:	Implementing improvement Strategies based on an integrated care pathway for early Psychosis
Principal Investigator:	Prof Andrew Gumley
GG&C HB site	Gartnavel Royal Hospital
Sponsor	NHS Greater Glasgow and Clyde
R&I reference:	GN20MH443
REC reference:	n/a
Protocol no: (including version and date)	V1.0; 01/05/20

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

1. **For Clinical Trials** as defined by the Medicines for Human Use Clinical Trial Regulations, 2004

   a. During the life span of the study GGHB requires the following information relating to this site
      i. Notification of any potential serious breaches.
      ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (www.nhsggc.org.uk/content/default.asp?page=s1411), evidence of such training to be filed in the site file.

2. **For all studies** the following information is required during their lifespan.
   a. First study participant should be recruited within 30 days of approval date.

NHS
Greater Glasgow and Clyde

b. Recruitment Numbers on a monthly basis
c. Any change to local research team staff should be notified to R&D team
d. Any amendments – Substantial or Non Substantial
e. Notification of Trial/study end including final recruitment figures
f. Final Report & Copies of Publications/Abstracts
g. You must work in accordance with the current NHS GG&C COVID19 guidelines and principles.

Please add this approval to your study file as this letter may be subject to audit and monitoring.

Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Mrs Elaine O'Neill
Senior Research Administrator

Appendix 2.4 NHS to NHS Letter of Access for Research

NHS
Greater Glasgow and Clyde

Administrator: Mrs Elaine O'Neill
Telephone Number: 0141 314 4001
E-Mail: elaine.o'neill2@ggc.scot.
Website: www.nhsggc.org.uk/r&d

Research & Development
Ward 11 - Dykebar Hospital
Grahamston Road
Paisley PA2 7DE

Kirsty McPhilemy
NHS Ayrshire and Arran
Ayrshire Central Hospital
Kilwinning Road
Ayr KA12 8SS

Dear Ms McPhilemy,

NHS to NHS - Letter of Access for Research

As an existing **NHS employee** you do not require an additional honorary research contract with this NHS organisation. We are satisfied that the research activities that you will undertake in this NHS organisation are commensurate with the activities you undertake for your employer. Your employer is fully responsible for ensuring such checks as are necessary have been carried out. Your employer has confirmed in writing to this NHS organisation that the necessary pre-engagement check are in place in accordance with the role you plan to carry out in this organisation. This letter confirms your right of access to conduct research through **NHS Greater Glasgow and Clyde** for the purpose and on the terms and conditions set out below. This right of access commences on **01/10/2020** and ends on **30/10/2020** unless terminated earlier in accordance with the clauses below.

You have a right of access to conduct such research as confirmed in writing in the letter of permission for research from this NHS organisation. Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving permission to conduct the project.

You are considered to be a legal visitor to **NHS Greater Glasgow and Clyde** premises. You are not entitled to any form of payment or access to other benefits provided by this organisation to employees and this letter does not give rise to any other relationship between you and this NHS organisation, in particular that of an employee.

While undertaking research through **NHS Greater Glasgow and Clyde** you will remain accountable to your employer **NHS Ayrshire and Arran** but you are required to follow the reasonable instructions of your nominated manager **Prof Andrew Gumley** in this NHS organisation or those given on her/his behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by this NHS organisation in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with **NHS Greater Glasgow and Clyde** policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with **NHS Greater Glasgow and Clyde** in discharging its duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on **NHS Greater Glasgow and Clyde** premises. Although you are not a contract holder, you must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of a contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and the Board via the **HR Department** prior to commencing your research role at the Board.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice (http://www.dh.gov.uk/assetRoot/04/06/92/54/04069254.pdf) and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

NHS Greater Glasgow and Clyde will not indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that this NHS organisation accepts no responsibility for damage to or loss of personal property.

We may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of this NHS organisation or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

If your circumstances change in relation to your health, criminal record, professional registration or suitability to work with adults or children, or any other aspect that may impact on your suitability to conduct research, or your role in research changes, you must inform the NHS organisation that employs you through its normal procedures. You must also inform your nominated manager in this NHS organisation.

Yours sincerely

Mrs Elaine O'Neill
Senior Research Administrator

cc: Michael.gunning@aapct.scot.nhs.uk

Appendix 2.3 Covid-19 Suspension of Recruitment Letter

Dr Karen Bell
R&D Manager
Research & Development Team
60 Lister Street
University Hospital Crosshouse
Kilmarnock
KA2 0LB
T: 01563 825850
E: Karen.Bell2@aapct.scot.nhs.uk

13th March, 2020

Dear Principal Investigator / Research Team

Covid-19: Suspension of recruitment to all hosted clinical trials/studies in NHS GG&C

In order to address the current and potential implications of the rapidly developing COVID-19 outbreak on our patient population, clinical and research teams, we have taken the difficult decision to ***suspend recruitment*** into all* clinical research studies within **NHS Ayrshire & Arran**.

This is an urgent safety measure being taken to ensure that patients, carers and staff, particularly those with (*or who are in routine, close contact with others who have*) underlying health conditions are not put at any unnecessary risk. The decision has been taken in close consultation with National Research Scotland and Chief Scientist Office colleagues, and mirrors actions being taken in all Scottish NHS Boards. Please contact your local R&D Office if you wish to discuss the undernoted advice, which will be updated as required.

As of Monday 16th March, please do not approach any patient regarding clinical study participation.

*A small number of exceptions to the above decision may apply as follows:

Patients who have already signed informed consent may continue to screen and register for a trial BUT ONLY where the investigator considers it safe in light of the prevailing situation, and it is in the patient's best interests to do so. The decision to continue as described, in light of this guidance, must be recorded in the Investigator Site File and patient notes, and notified to the R&D Office as an exception (see below).

- All activities related to current or upcoming Covid-19 research studies should continue where safe to do so
- Patients may, at the PI's discretion, still be approached about observational studies, pre-screening studies, etc., where this participation requires no additional hospital attendance by the patient
- Patients may be enrolled in a study that the patient's treating physician considers to be providing "essential clinical care"

If you wish to apply any of the above exceptions, you should notify the R&D Office using the following email address BEFORE proceeding**: Karen.Bell2@aapct.scot.nhs.uk**. Please include the following details of the study (PI, IRAS number, Title) along with a justification, and plan for ongoing recruitment including the availability of study specific staff.

At this stage follow up visits for currently-enrolled patients that **involve face-to-face contact**, either in hospital or at the patient's home, should be postponed with immediate effect and until further notice to mitigate the impact of COVID-19 unless the visits are deemed vital for patient safety purposes. In such circumstances, the PI should always assess the risk and act in the patient's interests.

Research teams are asked to comply with the following:

1) Work with sponsors to agree arrangements for carrying out follow-up (hospital or at-home) visits remotely wherever possible
2) Maintain contact with your patients to provide reassurance, to let them know about any changes in arrangements, and to encourage them to remain within the study
3) Postpone any external monitoring visits unless there is a subject safety issue. Where possible please make arrangements to participate in remote monitoring
4) Postpone any site initiation visits or site selection visits unless they involve studies related to COVID-19
5) Protocol deviations- The MHRA expect there to be an increase in protocol deviations but have requested that these are documented in the normal manner
6) IMP supplies for our hosted CTIMPs should be discussed with Sponsors and with your local Pharmacy team who support your study. All patients should continue to receive their Investigational Medicinal Product (IMP) if you as PI (or in discussion with the CI/Sponsor) deem this the right thing to do. Supply of these medications should be carried out in a manner deemed to be of lowest risk. If a courier is to be used, Participants must consent verbally to providing contact details for these shipping purposes.

MHRA advice is available at https://mhrainspectorate.blog.gov.uk/2020/03/12/advice-for-management-of-clinical-trials-in-relation-to-coronavirus/

HRA advice is available at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/covid-19-guidance-sponsors-sites-and-researchers/

Finally, for now, we recognise that our colleagues throughout the service are responding to an unprecedented set of circumstances. It may be that our research staff are asked to support the efforts of colleagues in providing care as this stress on the system continues. We will expect that research support staff will do whatever they can, while also recognising that a significant volume of research activity will continue – increasing SAE, AE, Protocol deviation reporting, ongoing follow-up, new activities seeing patients remotely. We will at all times respond pragmatically, and provide whatever capacity is available when requested.

Please forward this letter to the sponsor and chief investigators. Ongoing contingency planning is underway and further correspondence will follow should the situation change.

Should have any queries please direct them to myself **or Danielle Gilmour Danielle.Gilmour@aapct.scot.nhs.uk.**

Yours sincerely,

Dr Karen Bell

R&D Manager, NHS Ayrshire & Arran

Appendix 2.5 Ethical Approval for EXPAND

WoSRES
West of Scotland Research Ethics Service

NHS
Greater Glasgow and Clyde

Professor Andrew Gumley
Mental Health and Wellbeing
Gartnavel Royal Hospital,
1st Floor, Admin Building
University of Glasgow
Glasgow
G12 OXH

West of Scotland REC 3
Research Ethics
Clinical Research and Development
Dykebar Hospital
Grahamston Road
Paisley PA2 7DE

Date 02 April 2020
Direct line 0141 314 0211
E-mail WoSREC3@ggc.scot.nhs.uk

Dear Professor Gumley

Study title:	**Exploring the experiences of people with psychosis and type 2 diabetes: A qualitative Study**
REC reference:	**20/WS/0021**
Protocol number:	**264580**
IRAS project ID:	**264580**

Thank you for your email of 13 March 2020, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered in correspondence by a Sub-Committee of the REC A list of the Sub-Committee members is attached.

Confirmation of ethical opinion
On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion
The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Appendix 2.6 EXPAND Participant Information Sheet

University of Glasgow
Institute of Health & Wellbeing

NHS Ayrshire & Arran

EXPAND
Exploring Psychosis and Diabetes

Exploring the Experiences of People with *Psychosis* and Type 2 Diabetes (EXPAND): Participant Information Sheet (Version 2.0 24th January 2020).

1. What will participation involve?

You are being invited to take part in this research study because a member of your care team thought you might be interested in participating. The aim of the research project is to explore the experiences of people who have psychosis and type 2 diabetes.

Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information.

Participation is voluntary and you do not have to take part if you do not wish to. You will continue to receive the best quality of care whether you take part or not.

If you decide to take part in this study, you will be given a copy of this Participant Information Sheet and the signed consent form to keep.

2. **Who is conducting the research?**

The research is being carried out by Kirsty McPhilemy who is a clinical psychologist in training from the University of Glasgow. The research is being supervised by Professor Andrew Gumley, Professor of Psychological Therapy from the University of Glasgow, and Dr Everett Julyan, Consultant Psychiatrist from NHS Ayrshire & Arran.

3. **What is the purpose of the study?**

The purpose of the study is to try and better understand the experience of living with psychosis and type 2 diabetes. The study is being carried out as part of the requirements of the Doctorate in Clinical Psychology training course at the University of Glasgow.

The study will involve talking to people who have a diagnosis of psychosis and type 2 diabetes. We know from previous research that people with psychosis are 2-3 times more likely to have type 2 diabetes compared to the general population.

Hearing first hand experiences of living with both conditions is essential in helping clinicians and researchers increase their understanding of what it is like living with psychosis and type 2 diabetes and to develop strategies to further support people to live well.

People who choose to take part in the study will be interviewed about their experiences of living with both conditions and what they understand about their psychosis and type 2 diabetes diagnosis.

4. **Why have I been invited to participate?**

We are inviting people to take part who are currently receiving treatment for psychosis, and have a diagnosis of type 2 diabetes. We believe you may fit these criteria which is why you have been invited to take part.

You can take part in this study if:

- You are over 16 years old
- You have a diagnosis of psychosis *and* type 2 diabetes

5. **Do I have to take part?**

No, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without having to give a reason.

Your decision whether to take part or not to take part, or to take part and withdraw at a later stage, will not affect your routine treatment, your relationship with those providing your treatment or your relationship with staff in NHS Ayrshire & Arran.

6. **What will happen to me if I take part?**

If you decide to take part, Kirsty will give you more information about the study and answer any questions you may have. If you would still like to take part, she will arrange an appointment time with you. The appointments will take place in a clinic room in the community centre, or it may be possible to conduct the interview in your home.

Before you begin the interview, you will be asked to sign a consent form to say you agree to take part in the study.

Your interview will last around one hour and will be an informal discussion about your psychosis and type 2 diabetes.

The interviews will be audio recorded to make sure that what is written down in the study matches what participants have said. The digital recorder used for recordings will be encrypted to NHS standards. All recordings will be transcribed anonymously and saved on an encrypted University computer. None of your personal or identifiable information will be saved on University computers. Any information that may identify you, or anyone else you talk about, will be anonymised. Some quotes from your interview may be included in the research paper, but all identifiable information will be anonymised.

After you have taken part in the interview, Kirsty will send you a letter thanking you for your participation and summarising the main points from your own interview. You will be able to contact Kirsty if there is anything in the letter that you do not agree with.
Kirsty may follow up the interview with a telephone call to check-in with you, if this is felt appropriate.

Approximately 8-12 people will be invited to take part in the study. The study will be carried out in Ayrshire & Arran.

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

It is possible that talking about your experiences of your mental and physical health condition, and the care you receive for these, may impact your psychological wellbeing. If you become upset or distressed as a result of your participation in the research, the researcher will be able to help you access support from your Community Mental Health Team or other services provided by NHS Ayrshire & Arran. You can also suspend your interview, or end your participation in the research at any time.

8. **What are the possible benefits of taking part?**

Although we cannot guarantee that you will find any benefits from taking part in the research, you may find it a positive experience helping us develop a better understanding of what it is like to live with a long term mental and physical health condition.

9. **Will my taking part in this study be kept confidential?**

We will inform your GP, Psychiatrist and Keyworker that you are participating in the study and any contact you have with the research team will be recorded in your clinical notes that are available to your wider care team. This means that the researcher will have access to your clinical notes during your participation in the research study.

All information which is collected about you, or responses that you provide, during the course of the research will be kept strictly confidential. You will be identified by an ID number, and any information about you will have your name and address removed so that you cannot be recognised from it.

However, please note that should you disclose information concerning risk of harm to yourself or other persons, the researcher may need to inform staff members involved in your care. The researcher would always discuss this with you in the first instance and support you in conveying such sensitive information to others.

All data in electronic format will be stored on a secure password–protected University computer. No one outside of the research team or appropriate governance staff will be able to find out your name, or any other information which could identify you.

Your information will only be used for the purpose of this research project, and it will only be disclosed with your permission, except as required by law.

What if I withdraw from this research project?

You can withdraw from the study at any time. You do not have to provide a reason and if you withdraw you will continue to receive your usual care and treatment.
If you do withdraw from the study, any personally identifiable information about you will be destroyed. However, annonymised data already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the research team up to the time that you withdraw will form part of the research project results. If you do not want them to do this, you should choose not to participate in this study.

10. What will happen to my data?

We may be collecting and storing information from you in order to undertake this study. Research data will be securely encrypted and retained on a university computer on a restricted access network which adhere to General Data Protection Guidelines (GDPR). Any identifiable information will be stored in a locked filing cabinet held by the data custodian within the University of Glasgow. The University is responsible for looking after your information and using it properly. Personalised information will be destroyed at the end of the research project but other research data will be kept for ten years. Your data will not be passed on to a 3rd party.

Researchers from the University of Glasgow collect, store and process all personal information in accordance with the General Data Protection Regulation (2018).

We plan to publish the research in a scientific journal and may present the findings to others; however, you will not be identifiable.

During the course of the study, your data may be examined by a representative of the study sponsor, University of Glasgow, to ensure that the study has been conducted to proper standards.

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

It is anticipated that results of this research project will be published and/or presented to others. If this is the case, information will be provided in such a way that you cannot be identified. We will use quotes taking directly from individual interviews; however, you will not be identifiable based on these quotations and all information will be anonymised.

If you feel you would like to receive a copy of the findings, then please let Kirsty know and she would be happy to send you a copy.

12. Who is organising and funding the research?

The research is being sponsored by the University of Glasgow. The study is being carried out as part of the requirements of the Doctorate in Clinical Psychology training course at the University of Glasgow.

Investigators for the study are:

1. Ms Kirsty McPhilemy (email:)

2. Professor Andrew Gumley (email: Andrew.Gumley@glasgow.ac.uk; tel: 0141-211-3939)

No financial benefits are expected to arise from the conduct of the research.

13. Who has reviewed the study?

The project has been approved by the NHS West of Scotland ethics committee.

14. Contact for Further Information

If you wish further information on the study then please contact Kirsty McPhilemy, Mental Health and Wellbeing, Gartnavel Royal Hospital, 1st Floor, Admin Building, University of Glasgow, Glasgow G12 0XH or on by e-mail: 2356259m@student.gla.ac.uk.

15. What will happen if I want to make a complaint?

If you have any concerns about the study or the way it is conducted or if you want to complain about any aspect of this study, please contact Kirsty McPhilemy in the first instance (email:).

The normal NHS Ayrshire & Arran complaint mechanisms are also available to you at https://www.nhsaaa.net/about-us/feedback-and-complaints/

Thank you for reading this Participation Information Sheet

Appendix 2.7 EXPAND Participant Information Sheet

University of Glasgow
Institute of Health & Wellbeing

NHS Ayrshire & Arran

EXPAND

Exploring Psychosis and Diabetes

Identification Number:

Name of Researcher: Kirsty McPhilemy

CONSENT FORM

	Please initial box
I confirm that I have read and understood the Participant Information Sheet version 2.0 dated 24th January 2020.	☐
I have had the opportunity to think about the information and ask questions, and understand the answers I have been given.	☐
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my legal rights being affected.	☐
I confirm that I agree to the way my data will be collected and processed and that data will be stored for up to ten years in University archiving facilities in accordance with relevant Data Protection policies and regulations.	☐

I understand that all data and information I provide will be kept confidential and will be seen only by study researchers and regulators whose job it is to check the work of researchers. ☐

I agree that my name, contact details and data described in the information sheet will be kept for the purposes of this research project. ☐

I understand that if I withdraw from the study, my data collected up to that point will be retained and used for the remainder of the study. ☐

I agree to my interview being audio-recorded. ☐

I understand that the recorded interview will be transcribed word by word and the transcription stored for up to ten years in University archiving facilities in accordance with Data Protection policies and regulations. ☐

I understand that my information and things that I say in an interview may be quoted in reports and articles that are published about the study, but my name or anything else that could tell people who I am will not be revealed. ☐

I agree that the researcher can follow up after the interview via a telephone call if the content of the interview causes any distress. ☐

I agree that researchers can tell my GP, Psychiatrist and Keyworker that I am taking part in this study. ☐

I understand that any contact with the research team will be recorded by the researcher in my clinical notes that are made available to my wider care team. ☐

I agree that should significant concerns regarding my mental or physical health arise during my participation in the study that a member of an appropriate clinical team will be immediately informed. ☐

I agree to take part in the research study. ☐

_____ _____ _____

Name of participant Date Signature

_____ _____ _____

Researcher Date Signature

(1 copy for participant; 1 copy for researcher)

APPENDIX 2.7 EXPAND Participant Information Leaflet

Appendix 2.8 Participant Information Leaflet

Who Will I see?

You will see Kirsty McPhilemy (see picture below) who is a Trainee Clinical Psychologist

Kirsty will arrange to visit you to discuss the project and what participation involves. Kirsty will provide you with a Participant Information Sheet. Once you have read this and you are satisfied with what is involved in the study, you can decided whether or not you would like to take part.
There is no obligation for you to take part in the study.

Finding Out More

If you would like to find out more about the study then please speak to the person who gave you this leaflet or a member of your care team.

NHS Ayrshire & Arran

University of Glasgow Institute of Health & Wellbeing

EXPAND

Exploring Psychosis and Diabetes

Take part in research about your experience with psychosis and type 2 diabetes

NHS Ayrshire & Arran

University of Glasgow Institute of Health & Wellbeing

Expand Participant Information Leaflet (v1.0 30.09.19) IRAS ID: 264580

What is EXPAND?

The EXPAND project hopes to learn from people who live with both psychosis and type 2 diabetes.

Previous research has shown that people living with psychosis are up to three times more likely to be diagnosed with type 2 diabetes compared to those without psychosis.

Hearing from people with psychosis and type 2 diabetes is important in helping clinicians and researchers increase their understanding of what it is like living with both conditions and to develop strategies to support people to live well.

As part of this study we will be interviewing people who live with psychosis and type 2 diabetes.

Who is the EXPAND team?

The EXPAND project is being carried out by Kirsty McPhilemy who is a Clinical Psychologist in training from the University of Glasgow.

The project is being supervised by Professor Andrew Gumley, Professor of Psychological Therapies at the University of Glasgow, and Dr Everett Julyan, Consultant Psychiatrist from NHS Ayrshire & Arran.

What's Involved?

To find out more about the study, please speak to the person who gave you this leaflet or speak to your GP, Psychiatrist or Keyworker.

People who agree to take part in study will be interviewed about their experiences. Interviews will take place in a mutually agreed place and will last around 60 minutes.

You are under no obligation to take part.

Why am I being asked to take part?

If you have type 2 diabetes and psychosis then the EXPAND team would like to invite you to take part in the project.

You may also have been identified by a member in your care team as someone who is eligible to take part in the EXPAND project.

Appendix 2.9: Expand Major Research Project Proposal

Major Research Project Proposal

Name: Kirsty McPhilemy

Matriculation Number:

Academic Supervisor: Prof Andrew Gumley
Field Supervisor: Dr Everett Julyan

Date of Submission 28th January 2019

Version Number: 1.0

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Abstract

Background: People with serious mental illness have a reduced life expectancy of 15-20 years. This health inequality is striking, and largely attributable to physical illness. Type 2 diabetes is seen as one of the most pressing health inequality facing those with schizophrenia, 2-3 times more prevalent compared to that of the general population. Despite growing research into the complex relationship between schizophrenia and type 2 diabetes, less is known about how people experience life with both conditions. The limited qualitative research available has a focus on staff perceptions of supporting individuals with co-morbid schizophrenia and type 2 diabetes. There appears to be even less attempts to understand this phenomena using first hand accounts.

Aims: The study aims to explore how people with schizophrenia experience and manage their type 2 diabetes.

Methods: Interpretative phenomenological analysis (IPA) will be used to guide the design of the study, including data collection and subsequent analysis.

Applications: Results and key findings will be shared with participants, their care teams and key stakeholders. It is hoped this will help influence management and care of type 2 diabetes leading to better health outcomes for those with schizophrenia.

Introduction

It has been well documented that people with diagnosed schizophrenia experience poor health outcomes and high mortality rates with a reduced life span of 15-20 years compared to the general population (Tiihonen et al., 2009). This inequality is largely attributable to physical illness such as metabolic and cardiovascular disease, rather than factors associated directly to psychiatric illness, such as suicide (Disability Rights Commission, 2006). Co-morbidity of schizophrenia and type 2 diabetes (T2D) has been widely recognised as one of the more pressing health inequalities faced by individuals with schizophrenia, affecting 15-18% of the schizophrenia population, 2-3 times higher than that of the general population (De Hert et al., 2009).

Mental and physical health disorders often share a wide range of genetic, social and lifestyle related risk factors and thus the relationship between schizophrenia and T2D is complex. In the general population, risk factors associated with diabetes include obesity (Espeland, 2007), smoking, poor diet, sedentary behaviour (Liu et al., 2013), and poor sleep

(Cappucio et al.,2010). These risk factors are widely accepted to be present amongst people with schizophrenia, for example, with rates of smoking in schizophrenia to be estimated at 70% compared with 20% in the general population (Myles et al 2012). People with schizophrenia and other serious mental illness are amongst the most socially excluded from our society and routinely experience adverse social determinants of health including poor housing, social exclusion, low socio-economic status and unemployment. People with schizophrenia face further challenges with regards to equity of healthcare with evidence suggesting that diabetic patients with co-morbid serious mental illness are less likely to receive adequate standards of diabetic care (Frayne, 2005), with frequent diagnostic overshadowing being cited as an area of concern (RC PSYCH, 2010, Smith et al., 2013).

Historically, anti-psychotic medication has been the main treatment for people with schizophrenia and it poses a unique risk factor for T2D. Current research reports that second generation antipsychotics such as Clozapine and Olanzapine show notable benefits compared to their earlier counterparts; however, their use has been associated with abnormalities in glucose metabolism and dramatic weight gain is evident, which in some cases has led to fatal diabetic ketoacidosis (American Diabetes Association, 2004). It has also been suggested that the chronic hyper secretion of adrenalin; a diabetogenic hormone, which is released as a consequence of psychological stress associated with psychosis, makes schizophrenia itself an independent risk factor for developing type 2 diabetes (Thakore, 2004).

The risk of T2D posed to those with schizophrenia has been well documented and in 2015, the National Institute for Health Care and Excellence (NICE) published quality standards recommending adults with schizophrenia or psychosis should have regular and comprehensive physical health assessments with physical health interventions if necessary (NICE QS, 80, 2015). However, there is insufficient evidence to say how such interventions should be commissioned (National Collaborating Centre for Mental Health, 2014). Some research has suggested that efforts to improve outcomes have been hampered by negative staff attitudes and report that many mental health practitioners have limited training in physical care and that the monitoring of physical health by community mental health staff is generally unsatisfactory (Gournay 1996). Furthermore, mental health nurse training in the UK has historically been criticized for failing to deliver on physical health competencies (Department of Health, 2006). A literature review by Hultosjo & Hjelm (2010) looked at the evidence regarding the care requirements for individuals with psychotic disorders and at risk of, or with existing type 2 diabetes, and expressed the important role of mental health nurses and paid care workers in motivating diabetic care to help overcome impeding factors of

chronic mental illness such as apathy and avolition, which can have a detrimental effect in diabetic self-care. People with serious mental illness are often in frequent contact with primary care services although this does not necessarily mean the receive good physical health care. Improving the physical health of people with schizophrenia depends on holistic care from both mental and physical health staff who are aware of the problem and have a willingness to think of proactive approaches which will benefit the service user.

There appears to be a growing literature looking at lifestyle interventions to improve physical health outcomes in people with serious mental illness; however, these have been criticised due to high drop out rates (Vancampfort et al., 2012) and poor methodological quality (Rosenbaum, 2014). A recent Randomized Control Trial (RCT) by Holt and colleagues (2018) used a theory based, group structured education programme to target obesity in people with schizophrenia and psychosis and found it was neither clinically nor cost effective; however, participants were successfully recruited and retained, perhaps suggesting a clear interest in such interventions. Two other UK lifestyle intervention trials have also been unable to meet their primary outcome of reducing substance use in those with schizophrenia (Heslin et al 2017) and reducing cholesterol and cardiovascular risk in people with serious mental illness (Osborn et al., 2018). Intervention studies have therefore been inconclusive in their efforts to improve the physical health of people with serious mental illness.

Despite the growing research exploring the potential causes and epidemiology of T2D in schizophrenia and reported attempts to manage physical health with lifestyle interventions, less is known about how people with schizophrenia experience their physical health. How do people cope with co-morbid conditions manage their self-care and what are their health beliefs? El-Mallakh (2006) interviewed 11 respondents with comorbid schizophrenia and diabetes and reported psychiatric symptoms as major barrier to their diabetic self-care; however, noted that some were able to apply their acquired knowledge of managing their mental health onto their physical health condition as a useful strategy. Adherence to diabetic self-care can be difficult, requiring challenging life style changes for even those who possess high level of self-discipline (Fisher et al., 1997) and symptoms commonly experienced with schizophrenia, such as avolition and apathy, may pose a barrier to diabetic self-care. Of the limited qualitative research in the area, much has focussed on care staffs' perceptions in supporting service users to manage their conditions (Hultsjo & Hjelm, 2012, McBain et al., 2016) with very little research looking at the first-hand accounts of people living with comorbid schizophrenia and type 2 diabetes. The purpose of the present

study therefore is to fill a gap in the current literature and provide an insight into the experience of living with co-morbid schizophrenia and type 2 diabetes.

Aims

The aim of the current study is to explore how people with schizophrenia experience and manage their type 2 diabetes by using first-hand accounts.

Plan of Investigation

Method

Interpretative phenomenological analysis (IPA) (Smith, Flowers & Larkin, 2009) will be used to guide the design of the study, including data collection and subsequent analysis. This methodology has been chosen to allow the researcher to engage with participants' experiences of co-morbid chronic illness and attempt to make sense of their world through rigorous interpretation. IPA has an experiential focus, which places the participant as the expert of their own experiences and the idiographic level of analysis implies a focus on the particular, rather than the general. With its roots in phenomenology, it is interested in how people perceive and understand major life events. Double hermeneutics also plays an important role in the IPA process in that as the participant attempts to make sense of their world, the researcher must also attempt to critically capture and make sense of how the participant has arrived at their interpretation; by finding the 'insider's perspective' (Conrad, 1987).

Reflexivity

Husserl argued that human beings are sense-makers, constantly seeking to attach meaning to phenomena. Therefore, the researcher's own interpretation of data may be contextualised by their prior experiences and learning. For this reason, it is important to highlight that the researcher has a specific interest in the area of health psychology and the different health psychology models for understanding thoughts and behaviour related to physical health. In order to manage pre-conceptions and assumptions which may arise from this, the researcher will engage in the process of reflexivity by critically evaluating how fore-conceptions may influence the research (Finlay, 2009). It is hoped that this will help to avoid the researcher imposing their own ideas onto the participants.

Participants

Although often thought to benefit from using fewer participants (Smith et al., 1999;2007), there seems to be no right answer to the question of sample size in IPA research. There may be an argument for smaller samples being preferential in IPA given its commitment to idiography which seeks to understand the meaning of unique and often *subjective* phenomena. This is in contrast to the mainstream nomethic approach in psychology which often prefers large sample sizes and concerns itself with the rules that govern the general population, often explaining *objective* phenomena. Arguably, detailed interpretative accounts may be sacrificed in larger samples, as meaningful idiosyncrasies and unique experiences may become overlooked, running the risk of generalisation amongst participants (Smith et al., 2007). With this in mind, the study hopes to recruit a homogenous sample of 8-12 participants. Inclusion criteria will include: i) a clinical diagnosis of schizophrenia or schizo-affective disorder, and co-morbid type 2 diabetes and ii) participants over 16 years old. Exclusion criteria will include: i) those with affective psychosis ii) those under the Adults with Incapacity (Scotland) Act (2000) and ii) those who are unable to understand the study's aims and procedures. This is to ensure participants can engage well throughout the interview process and to optimise the likelihood of quality responses.

Recruitment

The researcher will approach mental health teams across NHS Ayrshire & Arran and third sector organisations including; Ayr Action for Mental Health (AAMH) in South Ayrshire and SAMH ALBA (Active Living Becomes Achievable) in North Ayrshire to help identify potential participants for recruitment. Additionally, the researcher will approach some General Practices in NHS Aryshire and Arran and ask for their help to identify potential participants using data from their practice computer systems.

Collecting Data

Semi-structured, in-depth interviews will be used to explore the experiences of people with co-morbid psychosis and type 2 diabetes. A topic guide (appendix A) will loosely guide the researcher and will allow flexibility to probe further into interesting responses from the participant or into an area not covered by the interview questions. Interviews will then be analysed using IPA with the aim of exploring the meanings which participants assign to their experiences.

Design

A short leaflet describing the study will be designed to be left in waiting rooms and given to staff to pass on to potential participants. If service users express an interest in participating in the study, they will be sent a patient information leaflet with further details and given at least 24 hours to consider taking part. The location of interviews will depend on where the patient feels most comfortable; either in their own homes or clinic room and therefore this will be arranged with the participant on an individual basis. A digital recorder encrypted to NHS standards will be used to record each interview. It will be anticipated that interviews will last up to one hour and participants will be able to take a break at any time. Recorded interviews will then be uploaded to an encrypted computer folder and analysed as detailed below. Recordings will be deleted one year after completion of the research project.

Analyses

The first stage of the analysis will be to listen back to the recordings to form verbatim transcripts. These will be read and re-read in order for the researcher to immerse themselves in the participant's world. This process will play an important role in locating richer and detailed sections of the participant's narrative as well as identifying any paradoxes and subsequently helping to form a model of each participant's experience.

The next stage will be the initial coding of the data and will involve making exploratory comments based on the original transcripts. Exploratory comments will be divided into descriptive, linguistic and conceptual comments. This coding process will lead to the development of emerging themes. These emerging themes will be clustered for each individual transcript. Recurrent themes will be noted using a theme table and those themes which occur most frequently, whilst depicting compelling and interesting portrayals of experience, will be chosen to be represented in the research paper.

Ethical Issues

Voluntary and informed consent will be sought, and participants will be able to withdraw from the study at any point without this having any impact on them. Participant anonymity will be respected throughout the research process and pseudonyms will be used in the write up to prevent identification of those taking part. The researcher will use the 'find and replace' function on Microsoft Word to change any names of individuals or places which may identify participants. The researcher will also make clear limitations of confidentiality to participants at the beginning of the research process and remind them of this throughout if necessary. Additionally, the researcher will also write a letter to the person responsible for

the participants care (e.g. psychiatrist, GP) to inform them of the individual's participation in the study.

The consent form and information leaflet will be made jargon free and easy to read. Participants will be encouraged to ask questions to allow ample opportunity to understand the research aims and procedures. In order to adhere to Good Clinical Practice (GCP) the researcher will check that each participant fully understands the patient information leaflet. If the participant has not read the patient information leaflet, then they will have time to do so and then given at leas 24 hours to consider their participation. The study will be sponsored jointly by the University of Glasgow and NHS Ayrshire and Arran. Approval will be sought by the Clinical Governance Department, NHS Ayrshire and Arran and Caldicott Guardian approval will be obtained.

Health and Safety Issues

The researcher may be required to visit participants in their homes to conduct interviews and will therefore follow local NHS procedures for lone working. Each home visit will be risk assessed beforehand by the researcher.

Financial Issues

The researcher may claim for travel expenses if interviews take place in the participants' homes.

Timetable

Proposal draft	November 2018
Proposal final	January 2019
Ethics Application	Jun 2019
Data Collection	Sept 2019 – Apr 2020
Data analysis and write up	May-Jul 2020
Submission of MRP	31st July 2020
Viva	3-4th Sept 2020

Practical Applications

It is hoped that those with co-morbid schizophrenia and type 2 diabetes, and those involved in their care, will benefit from the research study via dissemination of results and learning from the study. Those who participated in the study will be offered a copy of the executive summary, or a copy of the completed research project if this is requested. Results will also be disseminated to the mental health teams and GP practices who were involved in the recruitment of participants. It is hoped that this may help improve outcomes of those with co-morbid schizophrenia and type 2 diabetes by increasing an understanding of what it may

be like to live with both conditions. Additionally, publication of the research in a peer-reviewed journal (e.g. The Journal of Health Psychology) will help to share knowledge on a wider platform to help effect change by promoting an understanding of living with comorbid chronic physical and mental health conditions both at an individual and institutional level.

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